Clinical Policy Title:	CNS stimulants
Policy Number:	RxA.89
Drug(s) Applied:	Focalin XR®, Adhansia XR™, Aptensio XR™, Jornay PM™, Daytrana®, Quillichew ER®, Quillivant XR®, Cotempla XR-ODT®, Mydayis®, Adzenys ER™, Dyanavel XR®, Adzenys XR-ODT™
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

The following are the central nervous system (CNS) stimulants requiring prior authorization:

- amphetamine extended-release orally disintegrating tablets (Adzenys XR-ODT™)
- amphetamine extended-release oral suspension (Adzenys ER™, Dyanavel XR®)
- mixed salts of a single entity amphetamine product extended-release (Mydayis®)
- dexmethylphenidate extended-release (Focalin XR®)
- methylphenidate extended-release (Adhansia XR™, Aptensio XR™, Jornay PM™)
- methylphenidate transdermal system (Daytrana®)
- methylphenidate extended-release chewable tablets (Quillichew ER®)
- methylphenidate extended-release oral suspension (Quillivant XR®)
- methylphenidate extended-release orally disintegrating tablets (Cotempla XR-ODT®)

Extended-release methylphenidate and amphetamine products are indicated for attention deficit/hyperactivity disorder (ADHD).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
amphetamine ER oral suspension (Adzenys ER™)	ADHD	Patients 6 to 17 years: 6.3 mg (5 mL) PO once daily Adults: 12.5 mg (10 mL) PO once daily	6 to 12 years: 18.8 mg (15 mL)/day 13 years and older: 12.5 mg (10 mL)/day
amphetamine ER orally disintegrating tablet (Adzenys XR-ODT™)		Patients 6 to 17 years: 6.3 mg PO once daily Adults: 12.5 mg PO once daily	6 to 12 years: 18.8 mg/day 13 years and older: 12.5 mg/day
methylphenidate ER (Adhansia XR™)	ADHD	Patients 6 years of age and older: Starting dose 25 mg PO once daily,dose may be increased in increments of 10 to 15 mg at intervals of at least 5 days.	Pediatrics: 70 mg/day Adults: 85 mg/day

Dosing Information			
Drug Name	**Indication**	**Dosing Regimen**	**Maximum Dose**
methylphenidate ER (Aptensio XR™)	ADHD	Patients 6 years of age and older: Starting dose 10 mg PO once daily, dose may be increased weekly in increments of 10 mg per day.	60 mg/day
methylphenidate ER (Jornay PM™)		Patients 6 years of age and older: Starting dose 20 mg PO QHS, dose may be increased weekly in increments of 20 mg per day.	100 mg/day
methylphenidate ER orally disintegrating tablet (Cotempla XR-ODT®)		Patients 6 to 17 years: Starting dose 17.3 mg PO once daily day, dose may be increased weekly in increments of 8.6 mg to 17.3 mg per day.	51.8 mg/day
dexmethylphenidate ER (Focalin XR®)		Pediatric patients: Starting dose 5 mg PO once daily, dose may be increased weekly in increments of 5 mg per day. Adult patients: Starting dose 10 mg PO once daily, dose may be increased weekly in increments of 10 mg per day.	Pediatrics: 30 mg per day Adults: 40 mg per day
methylphenidate transdermal system (Daytrana®)		10 mg applied to the hip area (using alternating sites) 2 hours before an effect is needed and should be removed 9 hours after application	30 mg/9-hour patch per day
amphetamine oral suspension (Dyanavel XR®)		Patients 6 years and older: Starting dose 2.5 to 5 mg PO once daily, dose may be increased in increments of 2.5 mg to 10 mg per day every 4 to 7 days	20 mg/day
mixed salts of a single-entity amphetamine product extended release (Mydayis®)		Patients 13 years and older: Starting dose 12.5 mg PO once daily, dose may be increased in increments of 12.5 mg no sooner than weekly.	Pediatrics (13 to 17 years): 25 mg/day Adults: 50 mg/day
methylphenidate chewable tablet (Quillichew ER®)		Patients 6 years and older: Starting dose 20 mg PO once daily, dose may be increased weekly in increments of 10, 15 or 20 mg per day.	60 mg/day
methylphenidate ER oral suspension (Quillivant XR®)		Patients 6 years and older: Starting dose 20 mg PO once daily, dose may be increased weekly in increments of 10 to 20 mg per day.	60 mg/day

Dosage Forms

- Adzenys ER™ (amphetamine): Extended-release oral suspension, 1.25 mg/mL
- Adzenys XR-ODT™ (amphetamine): Extended-release orally disintegrating tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, 18.8 mg
- Adhansia XR™ (methylphenidate ER): Extended-release capsules, 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, 85 mg

- Aptensio XR™ (methylphenidate ER): Extended-release capsules, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg
- Jornay PM™ (methylphenidate ER): Extended-release capsules, 20 mg, 40 mg, 60 mg, 80 mg, 100 mg
- Cotempla XR-ODT® (methylphenidate ER orally disintegrating tablet): Extended-release orally disintegrating tablets, 8.6 mg, 17.3 mg, 25.9 mg
- Focalin XR® (dexmethylphenidate): Extended-release capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg
- Daytrana® (methylphenidate Transdermal System): Transdermal patch, 10 mg/9 hours, 15 mg/9 hours, 20 mg/9 hours, and 30 mg/9 hours
- Dyanavel XR® (amphetamine): Extended-release oral suspension, 2.5 mg/mL
- Mydayis® (amphetamine dextroamphetamine extended-release): Extended-release capsules, 12.5 mg, 25 mg, 37.5 mg, 50 mg
- Quillichew ER® (methylphenidate chewable): Extended-release chewable tablets, 20 mg, 30 mg, 40 mg
- Quillivant XR® (methylphenidate oral suspension): Extended-release oral suspension, 25 mg (5 mg/mL)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Member has a diagnosis of ADHD;
2. Member is 6 years of age or older;
3. Member meets one of the following (a or b):
   a. Failure of one preferred formulary extended-release amphetamine and one preferred formulary extended-release methylphenidate at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Request is for Adzenys ER™, Adzenys XR-ODT™, Cotempla XR-ODT®, Daytrana®, Dyanavel XR®, Quillichew ER®, or Quillivant XR® and documentation supports inability to use dosage forms available on the drug formulary (e.g., inability to swallow tablets or capsules);
4. Dose does not exceed the following
   a. Adhansia XR™: 85 mg per day (1 tablet per day);
   b. Adzenys ER™: 15 mL per day;
   c. Adzenys XR-ODT™: 12.5-18.8 mg per day (1 tablet per day);
   d. Cotempla XR-ODT®: 51.8 mg per day (2 tablets per day);
   e. Daytrana®: 30 mg per day (1 patch per day);
   f. Dyanavel XR®: 20 mg per day;
   g. Focalin XR®: 30 mg per day (pediatric patients), 40 mg per day (adults);
   h. Jornay PM™: 100 mg per day (1 tablet per day);
   i. Mydayis®: 50 mg per day;
   j. Quillichew ER®, Quillivant XR®, Aptensio XR™: 60 mg per day (1 tablet/capsule per day).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or member

has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the following:
   a. Adhansia XR™: 85 mg per day (1 tablet per day);
   b. Adzenys ER™: 15 mL per day;
   c. Adzenys XR-ODT™: 12.5-18.8 mg per day (1 tablet per day);
   d. Cotempla XR-ODT®: 51.8 mg per day (2 tablets per day);
   e. Daytrana®: 30 mg per day (1 patch per day);
   f. Dyanavel XR®: 20 mg per day;
   g. Focalin XR®: 30 mg per day (pediatric patients), 40 mg per day (adults);
   h. Jornay PM™: 100 mg per day (1 tablet per day);
   i. Mydayis®: 50 mg per day;
   j. Quillichew ER®, Quillivant XR®, Aptensio XR™: 60 mg per day (1 tablet/capsule per day).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ADHD: attention-deficit and hyperactivity disorder
CNS: central nervous system
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methylphenidate extended release (Ritalin LA®, Concerta®, Metadate CD®)	Concerta®: 18 - 36 mg PO once daily Ritalin LA®, Metadate CD®: 20 my PO once daily	Concerta®: 72 mg/day Ritalin LA®, Metadate®: 60 mg/day
amphetamine (Adderall XR®)	Patients 6-17 years: 10 mg PO once daily Adults: 20 mg PO once daily	Patients 6-12 years: 30 mg/day
dextroamphetamine (Dexedrine SR®)	5 mg PO once daily/twice daily	40 mg/day
Vyvanse® (lisdexamfetamine)	30 mg PO once daily	70 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - All CNS stimulants above: Hypersensitivity; use with monoamine oxidase (MAO) inhibitor, or within 14 days of last MAO inhibitor dose.
  - Daytrana®: Hypersensitivity; use with monoamine oxidase (MAO) inhibitor, or within 14 days of last MAO inhibitor dose; marked anxiety, tension, or agitation; glaucoma; tics or family history of Tourette's syndrome.

- Boxed Warning(s):
  - High potential for abuse and dependence

APPENDIX D: General Information

- Use of CNS stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychiatric illness. Evaluate for bipolar disorder prior to Jornay PM™ use.
- Sudden death has been reported in association with CNS stimulants at recommended doses in pediatric patients with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmias, or coronary artery disease.
- Increased risk of serotonin syndrome can occur when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans) but also during overdosage situations. If it occurs, discontinue Mydayis® and initiate supportive treatment.

References

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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updated grammar/formatting	04/2020	/2020
Policy was reviewed and updated. 1. Clinical policy title and lines of business updated. 2. Duration of approval for initial and continued therapy updated to 12 months. 3. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 4. Reference were updated.	01/27/2021	3/09/2021