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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	January 1, 2011
Subject:	Methylphenidates	**Page:**	1 of 8

Last Review Date: December 13, 2024

Methylphenidate Dexmethylphenidate

Description

Adhansia XR, Aptensio XR, Concerta, Cotempla XR-ODT*, Daytrana, Jornay PM, Metadate CD, Metadate ER, Relexxii, Methylin, Methylin-ER, Quillivant XR, QuilliChew ER, Ritalin, Ritalin LA, Ritalin-SR (methylphenidate)

Focalin, Focalin XR (dexmethylphenidate)

Azstarys (serdexmethylphenidate and dexmethylphenidate)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication

Background

Methylphenidate is a DEA schedule II drug and a CNS stimulant used in the treatment of attention deficit hyperactivity disorder (ADHD) and narcolepsy. The exact mechanism by which methylphenidate acts is unknown; however, it presumably increases dopamine and norepinephrine levels in the brain (1-18). Methylphenidate also has an off-label indication for depression, although published trials are limited in size and duration. Dexmethylphenidate is the more pharmacologically active form of methylphenidate (19).

Attention deficit disorder (ADD) is no longer a medical diagnosis, however, it is often used to refer to predominantly inattentive type ADHD and associated symptoms. The terms ADD and ADHD will be used throughout this policy (20).

For patients 22 years of age and older prior authorization and review is required for both diagnosis and quantity requested. For patients 21 years of age and younger, review is required if the total daily dose exceeds the FDA recommended daily limit.

Regulatory Status
FDA-approved indications: The products addressed by this policy are FDA-approved for use in one or both of the following conditions: attention deficit hyperactivity disorder (ADHD) and narcolepsy (1-18).

Off-Label Uses:
Methylphenidates can be used as adjunctive therapy in the treatment of resistant depression (19).

Methylphenidate has a boxed warning regarding the high potential of abuse and addiction and should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic and or abusive use can lead to marked tolerance and psychological dependence. Quantity limits based on the FDA-approved dosage guidelines help to reduce abuse, addiction, and dose dependent adverse effects (1-18).

Contraindications with the use of methylphenidate include marked anxiety, tension, agitation, glaucoma, tics, or a family history or diagnosis of Tourette's syndrome. Methylphenidate is contraindicated in patients currently using or within 2 weeks of using an MAO inhibitor (1-18).

The safety and efficacy have not been established for Adhansia XR, Azstarys, Daytrana, and Jornay PM in pediatric patients less than 6 years of age (2,15-17).

Related policies
Amphetamines, Provigil-Nuvigil

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Methylphenidates may be considered **medically necessary** if the conditions indicated below are met.

Methylphenidates may be considered **investigational** for all other indications**.**

Prior-Approval Requirements

Age 22 years of age or older*

*For patients 21 years of age and younger review is required if the total daily dose exceeds the FDA recommended daily limit.

Diagnoses

Patient must have **ONE** of the following:

1. Narcolepsy
2. Attention deficit disorder (ADD)
3. Attention deficit hyperactivity disorder (ADHD)
4. Depressive disorder **AND ONE** of the following:
    a. Used in combination with antidepressants
    b. Inadequate treatment response, intolerance, or contraindication to antidepressants

Adhansia XR, Azstarys, Daytrana, and Jornay PM

Patient must be 6 years of age or older

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 22 years of age or older - **NONE**
Age 21 years of age and younger

Adhansia XR, Azstarys, and Daytrana Patient must be 6 – 21 years of age

Pre - PA Quantity

- Concurrent therapy between Azstarys and other methylphenidates is **NOT** allowed

Medication / Strength	Quantity Limit	Daily Dosing Limits

Aptensio XR 10 mg, 15 mg Metadate CD 10 mg Methylin Chewable Tablets 2.5 mg, 5 mg, 10 mg Methylphenidate 5 mg, 10 mg Methylphenidate ER 10 mg Ritalin LA 10 mg	4 units per day	60 mg per day*
Aptensio XR 20 mg Metadate CD 20 mg Methylphenidate 20 mg Methylphenidate ER 20 mg QuilliChew ER 20 mg Ritalin LA 20 mg	3 units per day	
Aptensio XR 30mg Metadate CD 30 mg QuilliChew ER 30 mg Ritalin LA 30mg	2 units per day	
Aptensio XR 40 mg, 50 mg, 60 mg Metadate CD 40 mg, 50 mg, 60 mg QuilliChew ER 40 mg Ritalin LA 40 mg, 60 mg	1 unit per day	
Daytrana Patch 10 mg, 15 mg, 20 mg, 30 mg	2 patches per day	
Methylphenidate oral solution 5 mg/5 mL Methylphenidate oral solution 10 mg/5 mL	60 mL per day	
Quillivant XR oral suspension 25 mg/5 mL (5 mg/1 mL)	12 mL per day	
Concerta 18 mg, 27 mg, 36 mg	2 units per day	72 mg per day*
Relexxii 18 mg, 27 mg, 36 mg		
Concerta 54 mg	1 unit per day	
Relexxii 45 mg, 54 mg, 63 mg, 72 mg		
Adhansia XR 25 mg, 35 mg, 45 mg, 55 mg, 70 mg **(85 mg is reserved for age ≥ 18 only)**	1 unit per day	**Age 6-17:** 70 mg per day **Age 18-21:** 85 mg per day
Focalin 2.5 mg, 5 mg, 10 mg Focalin XR 5 mg, 10 mg	4 units per day	40 mg per day
Focalin XR 15 mg, 20 mg	2 units per day	
Focalin XR 25 mg, 30 mg, 35 mg, 40 mg	1 unit per day	

Jornay PM 20 mg, 40 mg	2 units per day	100 mg per day*
Jornay PM 60 mg, 80 mg, 100 mg	1 unit per day	

Combination therapies are subject to the highest cumulative mg/day dosing limit
Any combination of therapy may be subject to additional review

Medication	Quantity Limit	Daily Dosing Limits
Azstarys Concurrent therapy between Azstarys and other methylphenidates is **NOT** allowed.	1 unit per day	52.3mg/10.4mg per day

Prior - Approval Limits

Quantity

- Concurrent therapy between Azstarys and other methylphenidates is **NOT** allowed

Medication	Daily Dosing Limits
Adhansia XR	85 mg per day
Aptensio XR/ Metadate CD/ Methylin/ Methylphenidate / QuilliChew ER / Ritalin LA	60 mg per day
Concerta	72 mg per day
Daytrana Patch	60 mg per day
Focalin/Focalin XR	40 mg per day
Jornay PM	100 mg per day
Methylphenidate oral solution	60 mg per day
Quillivant XR oral suspension	60 mg per day
Relexxii	72 mg per day

Medication	Daily Dosing Limits
Azstarys Concurrent therapy between Azstarys and other methylphenidates is **NOT** allowed.	52.3mg/10.4mg per day

Medication	Daily Dosing Limits

with Approved Formulary Exception Only	
Cotempla XR-ODT **(Pediatric use only)**	51.9 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Methylphenidate is a DEA schedule II drug and a CNS stimulant which is FDA approved for attention deficit hyperactivity disorder (ADHD), and narcolepsy. Dexmethylphenidate is approved for the treatment of ADHD. The exact mechanism by which methylphenidate acts is unknown; however, it is presumed to increase dopamine and norepinephrine levels in the brain. Methylphenidate has a boxed warning for a high potential of abuse and addiction (1-18).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of methylphenidate products while maintaining optimal therapeutic outcomes.

References

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Policy History

Date	Action
December 2011	New Policy
October 2010	Addition of Focalin XR 40mg to product line with the package insert updated to include a 40mg maximum dose for adults; therefore, the maximum daily dose for Focalin products will change from 30mg per day to 40mg per day (9).
September 2012	Annual editorial review and reference update
June 2013	Annual editorial review and reference update
September 2014	Annual editorial review and reference update
May 2015	Addition of Aptensio XR
June 2015	Annual review and reference update Changed Policy # from 5.07.03 and sub-heading from Endocrine and Metabolic Drugs
December 2015	Addition of QuilliChew
March 2016	Annual review Policy number change from 5.06.25
September 2016	Annual review and reference update. Change in coverage from 21 years of age or younger for Pre-PA limits Addition of age limits on Daytrana for 6 years of age and older
December 2016	Annual review
July 2017	Addition of Cotempla XR-ODT
September 2017	Annual review
January 2018	Addition of Methylphenidate ER (OSM)
March 2018	Annual review
August 2018	Addition of Jornay PM
November 2018	Annual review and reference update

March 2019	Annual review and reference update. Addition of Adhansia XR
November 2019	Addition of statement for Pre-PA “Any combination of therapy may be subject to additional review”
December 2019	Annual review
December 2020	Annual review and reference update. Relexxii requires formulary exception + PA
March 2021	Annual review
April 2021	Addition of Azstarys to policy
June 2021	Annual review and reference update
September 2021	Annual review
December 2021	Revised Pre-PA chart to group all medications with the same mg/day. Also added quantity limits per day for Pre-PA. Moved Cotempla XR-ODT to FE with PA only. Moved Jornay PM to Pre-PA and PA without MFE
March 2022	Annual review and reference update. Per SME, changed “depression” indication to “depressive disorder” and added the requirement “used in combination with antidepressants” OR “inadequate treatment response, intolerance, or contraindication to antidepressants”
December 2022	Annual review. Changed policy number to 5.60.025
March 2023	Annual review
December 2023	Annual review and reference update
January 2024	Per FEP, moved Relexxii from FE + PA to just PA
March 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.