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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	January 1, 2011
Subject:	Methylphenidates	**Page:**	1 of 6

Last Review Date: March 12, 2021

Methylphenidate Dexmethylphenidate

Description

Adhansia XR, Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Jornay PM*, Metadate CD, Metadate ER, Relexxii* [Methylphenidate ER (OSM)], Methylin, Methylin-ER, Quillivant XR, QuilliChew ER, Ritalin, Ritalin LA, Ritalin-SR, Focalin, Focalin XR (Methylphenidate 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 which is FDA approved for attention deficit disorder (ADD), 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 (1-16). Methylphenidate also has an off-label indication for depression, although published trials are limited in size and duration (17).

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

The products addressed by this policy are FDA-approved for use in one or more of the following conditions: attention deficit disorder (ADD), attention deficit hyperactivity disorder (ADHD) and narcolepsy (1-16).

Off Label Uses:
Methylphenidates can be used as adjunctive therapy in the treatment of resistant depression (17).

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 (1-16).

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 (1-16).

Safety and efficacy has not been established for Adhansia XR, Daytrana, and Jornay PM in children under six years old (2,15-16).

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.

Methylphenidate and dexmethylphenidate may be considered **medically necessary** for the treatment of narcolepsy, attention deficit disorder, attention deficit hyperactivity disorder, or depression.

Methylphenidate and dexmethylphenidate 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. Depression

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

Pre - PA Quantity

Medication	Daily Dosing Limits
Adhansia XR (85 mg is reserved for Age ≥ 18 only)	Age 6-17: 70 mg per day Age 18-21: 85 mg per day
Aptensio / 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
Cotempla XR-ODT (Pediatric use only)	51.9 mg per day

Methylphenidate oral solution	60 mg per day
Quillivant XR oral suspension	60 mg per day

*Any combination of therapy may be subject to additional review

Prior - Approval Limits

Quantity

Medication	Daily Dosing Limits
Adhansia XR	85 mg per day
Aptensio / 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
Cotempla XR-ODT (Pediatric use only)	None
Methylphenidate oral solution	60 mg per day
Quillivant XR oral suspension	60 mg per day

Medication with approved formulary exception only	Daily Dosing Limits
Jornay PM	100 mg per day
Relexxii	72 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 disorder (ADD), 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 (1-16).

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

References

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15. Jornay PM [package insert]. Manati, Puerto Rico: Ironshore Pharmaceuticals & Development, Inc.; April 2019.
16. Adhansia XR [package insert]. Wilson, NC: Purdue Pharmaceuticals L.P.; July 2019.
17. Paktar AM, Pae C, et al. A randomized, double-blind, placebo-controlled trial of augmentation with an extended release formulation of methylphenidate in outpatients with treatment-resistant depression. *J Clin Psychopharm*. 26(6):653-656. Dec 2006.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on

March 12, 2021 and is effective on April 1, 2021.