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	TTER HEALTH®			
Coverage	Policy/Guideline			
Name:	Methylphenidates		Page:	1 of 5
Effective Date: 4/16/2025			Last Review Date:	3/2025
A	□Illinois	□Florida	□Florida Kids	
Applies to:	⊠New Jersey	□Maryland	□Michigan	
	□Pennsylvania Kids	□Virginia		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for methylphenidate products under the patient's prescription drug benefit.

Description:

FDA-approved Indications

Aptensio XR

Aptensio XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

Limitations of Use

Pediatric patients younger than 6 years of age experienced higher plasma exposure than patients 6 years and older at the same dose and high rates of adverse reactions, most notably weight loss.

Concerta

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.

Cotempla XR-ODT, Daytrana

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

Focalin, Focalin XR, QuilliChew ER, Quillivant XR

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Jornay PM

Jornay PM is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

Metadate CD

Metadate CD is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 15 years of age.

Methylin Oral Solution

Methylin is indicated for the treatment of:

 Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older

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Narcolepsy

Methylphenidate Chewable Tablets

Attention Deficit Disorders

Methylphenidate hydrochloride chewable tablets are indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

Narcolepsy

Methylphenidate Extended-Release, Ritalin

These products are indicated for the treatment of:

- Attention Deficit Hyperactivity Disorders (ADHD) in pediatric patients 6 years and older and adults
- Narcolepsy

Methylphenidate LA, Ritalin LA

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), in pediatric patients 6 to 12 years of age.

Methylphenidate Osmotic Extended-Release, Relexxii

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older.

Compendial Uses

- Narcolepsy ^{19-21,25}
- Cancer-related fatigue ^{21,26-27}

Applicable Drug List:

Reference Formulary for specific drugs

Policy/Guideline:

Documentation for Initial Requests for all indications:

For non-preferred medication requests, the patient is unable to take two (2) formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

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Coverage Criteria

Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires).
- If the patient is 5 years of age or younger, the patient continues to have ADHD/ADD symptoms despite participating in evidence-based behavioral therapy (e.g., parent training in behavior management (PTBM), behavioral classroom interventions).

Cancer-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out.

Narcolepsy

Authorization may be granted when the patient has a diagnosis of narcolepsy when ALL of the following criteria are met:

- The requested drug is being prescribed by, or in consultation with, a sleep specialist.
- The diagnosis has been confirmed by a sleep study.

Continuation of Therapy

Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

- The patient achieved or maintained improvement in their signs and symptoms of ADHD/ADD from baseline.
- The patient's need for continued therapy has been assessed within the previous year.

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Cancer-Related Fatigue

Authorization may be granted when the requested drug is being prescribed for the treatment of cancer-related fatigue after other causes of fatigue have been ruled out when ALL of the following criteria are met:

- The patient has achieved or maintained improvement in cancer-related fatigue from baseline.
- The patient's need for continued therapy has been assessed within the previous year.

Narcolepsy

Authorization may be granted when the patient has a diagnosis of narcolepsy when the following criteria is met:

 The patient has achieved or maintained improvement in daytime sleepiness with narcolepsy from baseline.

Approval Duration and Quantity Restrictions:

Approval:

Attention-Deficit Hyperactivity Disorder (ADHD) or Attention-Deficit Disorder (ADD): Approve 12 months

Narcolepsy: Approve 12 months

Cancer-related fatigue: Approve 12 months

Quantity Level Limit: Reference formulary for drug specific quantity level limits

References:

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- 2. Concerta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2023.
- 3. Cotempla XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC.; June 2021.
- 4. Daytrana [package insert]. Miami, FL: Noven Therapeutics, LLC; April 2024.
- 5. Focalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
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- 7. Jornay PM [package insert]. Morrisville, NC: Ironshore Pharmaceuticals Inc.; October 2023.
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