

PHARMACY COVERAGE GUIDELINE

APTENSIO XR™ (methylphenidate hydrochloride extended release) capsule
AZSTARYS™ (serdexmethylphenidate and dexamethylphenidate) capsule
COTEMPLA XR-ODT™ (methylphenidate hydrochloride extended release) tablet
DAYTRANA® (methylphenidate) transdermal patch
JORNAY PM™ (methylphenidate hydrochloride extended release) capsule
Methylphenidate ER capsule
Methylphenidate transdermal patch
QUILLICHEW ER® (methylphenidate hydrochloride extended release) tablet
RITALIN LA® (methylphenidate hydrochloride extended release) capsule
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for [APTENSIO XR](#) (methylphenidate hydrochloride extended release), [AZSTARYS](#) (serdexmethylphenidate and dexamethylphenidate), [COTEMPLA XR-ODT](#) (methylphenidate hydrochloride extended release), [DAYTRANA](#) (methylphenidate), [JORNAY PM](#) (methylphenidate hydrochloride extended release),

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Methylphenidate ER generic, **Methylphenidate Patch** generic, **QUILLICHEW ER** (methylphenidate hydrochloride extended release), and **RITALIN LA** (methylphenidate hydrochloride extended release)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a psychiatrist or in consultation with a psychiatrist

Indication

- Attention Deficit Hyperactivity Disorder (ADHD)

Age Requirement

- 6 years of age or older

Baseline Clinical Evaluation

- Confirmed diagnosis of ADHD

Alternative Therapies

- Failure, contraindication, or intolerance to **ONE** drug from **BOTH** of the following:
 - Generic oral extended-release methylphenidate OR generic extended-release dexamethylphenidate-based agent (e.g., generic Concerta, generic Metadate CD, generic Ritalin LA, dexamethylphenidate ER)
 - Generic oral extended-release dextroamphetamine with amphetamine extended-release (e.g., generic Adderall XR) OR oral generic extended-release dextroamphetamine **OR** Vyvanse (lisdexamfetamine)

Brand Specific Criteria

- **Aptensio XR:** Failure, contraindication, or intolerance to **generic methylphenidate hydrochloride ER capsule**
- **Daytrana** patch: Failure, contraindication, or intolerance to **generic methylphenidate patch**

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- Have failure, contraindication or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous, or a problem (i.e., multiple providers, multiple pharmacies, or multiple controlled substances)
- No known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems
- No history of uncontrolled psychiatric mood disorder (e.g., depression, suicide history, bipolar disorder, psychotic disorder)
- No FDA-labeled contraindications:
 - Known hypersensitivity to methylphenidate or amphetamine products
 - Use of monoamine oxidase inhibitor (MAOI) within the past 14 days
 - **Additional for Daytrana and generic methylphenidate patch:**
 1. Marked anxiety, tension, or agitation
 2. Glaucoma
 3. Tics or a family history or diagnosis of Tourette's syndrome

Documentation Requirements

- A completed request form must be submitted, including:
 - Chart notes
 - Lab results
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy)

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

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Prescriber Qualification

- Continues to be seen by a psychiatrist or in consultation with a psychiatrist

Clinical Response

- **TWO** of the following:
 - At least 50% reduction from baseline in core symptoms of hyperactivity, impulsivity, and attention
 - At least 50% improvement from baseline in SKAMP rating scale
 - Improved attention and social skills
 - No aggressive behaviors

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- **Aptensio XR:** Failure, contraindication, or intolerance to **generic methylphenidate hydrochloride ER capsule**
- **Daytrana** patch: Failure, contraindication, or intolerance to **generic methylphenidate patch**
- Have failure, contraindication or intolerance with three generic equivalents (when available) for at least three months each. Note: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous, or a problem (i.e., multiple providers, multiple pharmacies, or multiple controlled substances)
- No development of contraindications or significant adverse drug effects including:
 - Known hypersensitivity to methylphenidate or amphetamine products
 - Use of monoamine oxidase inhibitor (MAOI) within the past 14 days
 - Psychotic or manic symptoms
 - Priapism
 - Serious cardiovascular events (e.g., stroke, myocardial infarction)
 - Peripheral vasculopathy (e.g., Raynaud's phenomenon)
 - **Additional for Daytrana and generic methylphenidate patch:**

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1. Marked anxiety, tension, or agitation
2. Glaucoma
3. Tics or a family history or diagnosis of Tourette's syndrome
4. Chemical leukoderma or signs of skin depigmentation
5. Contact sensitization with erythema, edema, papules, & vesicles that has not improved within 48 hours or has spread beyond the patch site

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in ADHD
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year
-

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
 2. Off-Label Use of Cancer Medications
-

Description:

Aptensio XR (methylphenidate), Azstarys (serdexmethylphenidate and dexamethylphenidate), Cotempla XR-ODT (methylphenidate), Daytrana (methylphenidate transdermal system), Jornay PM (methylphenidate), methylphenidate ER, methylphenidate patch, Quillichew ER (methylphenidate) and Ritalin LA (methylphenidate) are central nervous system stimulants indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.

ADHD is one of the most commonly diagnosed neurobehavioral disorders of childhood. It is more frequently diagnosed in males than in females. ADHD is characterized by inattention, hyperactivity that exceeds the usual

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developmental pattern, impulsivity that impair activities of daily living, and/or inattention that occur in more than one setting and affect function (e.g., academic, social, emotional, etc.). The symptoms must not be better accounted for by another mental disorder.

Comorbidities are also common and may include mood disorder, anxiety disorder, substance abuse, tics, learning difficulties, and disruptive behaviors such as oppositional defiance or conduct disorder. Symptoms can persist into adolescence and into adulthood.

The published literature suggests that central nervous system stimulant medications are considered first line therapy in uncomplicated ADHD. Methylphenidate or mixed amphetamine salts, or dextroamphetamine are often recommended as first line therapy. Evidence for the use of methylphenidate is derived from well-designed efficacy and safety trials. Due to limited number of trial information the strength of evidence for the other stimulants is ranked as fair.

Treatment goals include improved relationships with parents, teachers, siblings, or peers (e.g., plays without fighting at recess); improved academic performance (e.g., completes academic assignments); and improved rule following (e.g., does not talk back to the teacher).

Response to treatment is demonstrated by objective measurement of reduction in core symptoms and/or improvement in target goals (e.g., 40-50% reduction in core symptoms compared with baseline and decreased proportion of missing assignments from 60% to 20%). Core symptoms can be monitored through the use of ADHD-specific rating scales and target symptoms can be monitored through a daily report card or periodic narrative reports from the child's teacher.

Treatment failure is defined by lack of satisfactory improvement in core symptoms of ADHD at the maximum dose or the occurrence of intolerable adverse effects. It is important to differentiate lack of response from rebound effects as the medication wears off. With lack of response there is no improvement in core symptoms. With rebound, there is an initial improvement in core symptoms, but near the end of the expected duration of action, there may be a recurrence or worsening of symptoms.

When one stimulant fails to manage the condition due to an inadequate response, it is suggested to change to another one of the first line stimulants. Approximately 50% of individuals not responding to one stimulant may respond to the other as side effects may occur with one type of stimulant but not another.

It is further suggested that if first line stimulants are ineffective, non-stimulant medications may be added or used as monotherapy. Use of non-stimulant medications may be beneficial in situations such as concerns about substance abuse or diversion, tic disorder, sleep problems, anxiety, psychosis, aggression, or cardiac abnormalities associated with use of stimulants. Non-stimulant medications may include atomoxetine, clonidine,

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guanfacine, and antidepressants (e.g., tricyclic antidepressants, bupropion, selective serotonin reuptake inhibitors).

There are many agents available with brand and generic options for the treatment of ADHD. Several agents are available as both immediate acting and long acting formulations. Comparative trials of stimulant medications are lacking, but it is apparent that all stimulant medications have similar effects and adverse effects and given the extensive evidence of efficacy and safety, they still remain agent first choice. There are clinically meaningful differences in dosing, time to onset, route, duration of action, and cost among the various compounds. Sustained-release formulations of stimulants may show benefit over immediate release forms at specific times of day depending on the pharmacokinetics of the specific formulation used, but overall differences on safety and efficacy are not found.

For individuals with swallowing difficulties, many capsule forms of extended release stimulants can be opened and sprinkled onto food. Liquid formulations are also available, and some products have a chewable dosage form that can be used.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Attention Deficit Hyperactivity Disorder (ADHD)

- ADHD types:
 - Inattentive Type, at least 6 of the following symptoms must have persisted for at least 6 months
 - Lack of attention to details/careless mistakes
 - Lack of sustained attention
 - Poor listener
 - Failure to follow through on tasks
 - Poor organization
 - Avoids tasks requiring sustained mental effort
 - Loses things
 - Easily distracted
 - Forgetful
 - Hyperactive-Impulsive Type, at least 6 of the following symptoms must have persisted for at least 6 months
 - Fidgeting/squirming
 - Leaving seat
 - Inappropriate running/climbing

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- Difficulty with quiet activities
- "On the go"
- Excessive talking
- Blurting answers
- Can't wait turn
- Intrusive
- Combined Type requires both inattentive and hyperactive-impulsive criteria to be met

ADHD medications – stimulants: [Note may not be a complete list and some products may have been discontinued or new products have come onto market]

| Methylphenidate-type products: | | |
|---------------------------------------|---------------|---|
| Methylphenidate | | |
| Adhansia XR | ER Cap 24 h | 25, 35, 45, 55, 70, 85 mg |
| Aptensio XR | ER Cap 24 h | 10, 15, 20, 30, 40, 50, 60 mg |
| Concerta | ER Tab | 18, 27, 36, 54 mg |
| Cotempla XR-ODT | ER ODT 24 h | 8.6, 17.3, 25.9 mg |
| Daytrana | Transdermal | 10 mg/9 hr, 15 mg/9 hr, 20 mg/9 hr, 30 mg/ 9 hr |
| Jornay PM | ER Cap 24 h | 20, 40, 60, 80, 100 mg |
| Metadate CD | ER Cap | 10, 20, 30, 40, 50, 60 mg |
| Metadate ER | ER Tab | 20 mg |
| Methylin | Tab chewable | 2.5, 5, 10 mg |
| | Solution | 5 mg / 5 mL, 10 mg / 5 mL |
| Methylphenidate | Tab | 5, 10, 20 mg |
| | Tab chewable | 2.5, 5, 10 mg |
| | Solution | 5 mg / 5 mL, 10 mg / 5 mL |
| | Transdermal | 10 mg/9 hr, 15 mg/9 hr, 20 mg/9 hr, 30 mg/ 9 hr |
| Methylphenidate ER | ER Tab | 10, 18, 20, 27, 36, 54 mg |
| Methylphenidate ER | ER Tab 24 h | 18, 27, 36, 54 mg |
| Methylphenidate ER (CD) | ER Cap | 10, 20, 30, 40, 50, 60 mg |
| Methylphenidate ER (LA) | ER Cap 24 h | 20, 30, 40 mg |
| Quillichew ER | ER Tab | 20, 30, 40 mg |
| Quillivant XR | ER Suspension | 25 mg / 5 mL |
| Relexxii | ER Tab | 18, 27, 36, 45, 54, 63, 72 mg |
| Ritalin | Tab 24 h | 5, 10, 20 mg |
| Ritalin LA | ER Cap 24 h | 10, 20, 30, 40 mg |
| Ritalin SR | ER Tab | 20 mg |
| Dexmethylphenidate | | |
| Dexmethylphenidate | Tab | 2.5, 5, 10 mg |

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| | | |
|---|-------------|--|
| Dexmethylphenidate ER | ER Cap 24 h | 5, 10, 15, 30, 40 mg |
| Focalin | Tab | 2.5, 5, 10 mg |
| Focalin XR | ER Cap 24 h | 5, 10, 15, 20, 25, 30, 35, 40 mg |
| Serdexmethylphenidate and Dexmethylphenidate | | |
| Azstarys | Cap | 26.1/5.2, 39.2/7.8, 52.3/10.4 mg |
| Listing does not imply formulary status or need for prior authorization or need step-therapy | | |
| Amphetamine-type products: | | |
| Amphetamine | | |
| Adzenys XR-ODT | Tab ODT 24h | 3.1, 6.3, 9.4, 12.5, 15.7, 18.8 mg |
| Dyanavel XR | Suspension | 2.5 mg/mL |
| Evekeo | Tab | 5, 10 mg |
| Amphetamine sulfate | Tab | 5, 10 mg |
| Mixed salts: Amphetamine (25%) / Dextroamphetamine (75%) | | |
| Adderall | Tab | 5, 7.5, 10, 12.5, 15, 20, 30 mg |
| Adderall XR | ER Cap 24 h | 5, 10, 15, 20, 25, 30 mg |
| Amphetamine / Dextroamphetamine | Tab | 5, 7.5, 10, 12.5, 15, 20, 30 mg |
| | ER Cap 24 h | 5, 10, 15, 20, 25, 30 mg |
| Dextroamphetamine | | |
| Dexedrine | ER Cap 24 h | 5, 10, 15 mg |
| Dextroamphetamine | Tab | 5, 10 mg |
| | Solution | 5 mg / 5 mL |
| Dextroamphetamine ER | ER Cap 24 h | 5, 10, 15 mg |
| ProCentra | Solution | 5 mg / 5 mL |
| Xelstrym | Transdermal | 4.5 mg/9 hr, 9 mg/9 hr, 13.5 mg/9 hr, 18 mg/9 hr |
| Zenzedi | Tab | 2.5, 5, 7.5, 10, 15, 20, 30 mg |
| Lisdexamfetamine | | |
| Vyvanse | Cap | 10, 20, 30, 40, 50, 60, 70 mg |
| Methamphetamine | | |
| Desoxyn | Tab | 5 mg |
| Methamphetamine | Tab | 5 mg |
| Listing does not imply formulary status or need for prior authorization or need step-therapy | | |

ADHD medications – non-stimulants: [Note may not be a complete list and some products may have been discontinued or new products have come onto market]

| | | |
|--|-----|--------------------------------|
| Norepinephrine re-uptake inhibitor | | |
| Atomoxetine (Strattera) | Cap | 10, 18, 25, 40, 60, 80, 100 mg |
| Clonidine – central alpha-2 agonist | | |

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| | | |
|---|-------------|------------------|
| Catapres | Tab | 0.1, 0.2, 0.3 mg |
| Clonidine | Tab | 0.1, 0.2, 0.3 mg |
| Clonidine ER | ER Tab 12 h | 0.1 mg |
| Kapvay (clonidine ER) | ER Tab 12 h | 0.1, 0.2 mg |
| Guanfacine – central alpha-2a agonist | | |
| Guanfacine | Tab | 1, 2 mg |
| Guanfacine ER | ER Tab 24 h | 1, 2, 3, 4 mg |
| Intuniv (guanfacine ER) | ER Tab 24 h | 1, 2, 3, 4 mg |
| Tenex | Tab | 1, 2 mg |
| Listing does not imply formulary status or need for prior authorization or need step-therapy | | |

Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) rating scale:

- A validated 13-item teacher-rated scale that assesses manifestations of ADHD in a classroom setting
- The rating scale consists of 13 items rated on a 7-point impairment scale (0 = normal to 6 = maximal impairment)
- The combined scores for the SKAMP are obtained by summing the values of all 13 items
- Subscale scores for attention (items 1-4), behavior (items 5-8), quality of work (items 9-11) and compliance (items 12-13) are obtained by summing the values of their corresponding items

| | Impairment Scale 0-7 |
|---|----------------------|
| 1. Getting started on assignments for classroom periods | 1 2 3 4 5 6 7 |
| 2. Sticking with tasks or activities for the allotted time | 1 2 3 4 5 6 7 |
| 3. Attending to an activity or a discussion of the class | 1 2 3 4 5 6 7 |
| 4. Stopping and making transition to the next period | 1 2 3 4 5 6 7 |
| 5. Interacting with other children | 1 2 3 4 5 6 7 |
| 6. Interacting with the teacher or aide | 1 2 3 4 5 6 7 |
| 7. Remaining quiet according to classroom rules | 1 2 3 4 5 6 7 |
| 8. Staying seated according to classroom rules | 1 2 3 4 5 6 7 |
| 9. Completing assigned work | 1 2 3 4 5 6 7 |
| 10. Performing work accurately | 1 2 3 4 5 6 7 |
| 11. Being careful and neat while writing or drawing | 1 2 3 4 5 6 7 |
| 12. Complying with the teacher's usual requests or directions | 1 2 3 4 5 6 7 |
| 13. Following the rules established for the classroom | 1 2 3 4 5 6 7 |

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Resources:

Aptensio XR (methylphenidate) extended-release capsule product information, revised by Rhodes Pharmaceuticals L.P. 10-2023. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed February 17, 2025.

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