BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

APTENSIO XR™ (methylphenidate hydrochloride extended release) capsule
AZSTARYS™ (serdexmethylphenidate and dexmethylphenidate) 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 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.

Criteria:

- **Criteria for initial therapy:** Aptensio XR, Azstarys, Cotempla XR-ODT, Daytrana, Jornay PM, methylphenidate ER or methylphenidate patch, Quillichew ER, Ritalin LA, and/or generic equivalent (if

available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist

2. Individual is 6 years of age or older

3. Individual has a confirmed diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)

4. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for a trial of **ONE** drug from **BOTH** of the following:
    a. A generic oral extended-release methylphenidate **OR** a generic extended-release dexmethylphenidate-based agent (such as generic Concerta, generic Metadate CD and generic Ritalin LA, dexmethylphenidate ER)
    b. Generic oral extended-release dextroamphetamine with amphetamine extended-release (e.g., generic Adderall XR) **OR** oral generic extended-release dextroamphetamine **OR** Vyvanse (lisdexamfetamine)

5. **Additional criteria** for **brand Aptensio XR (methylphenidate hydrochloride extended release) capsule** : Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for the **generic methylphenidate hydrochloride ER capsule** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. **Additional criteria** for **brand Daytrana (methylphenidate) patch**: Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for the **generic methylphenidate patch** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. **If available:** Individual has documented failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. There is 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)

9. There are no known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems

10. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression history of suicide, bipolar disorder, or psychotic disorder

11. There are **NO** FDA-label contraindications:
    a. Known hypersensitivity to methylphenidate or amphetamine products
    b. Currently using or use within the preceding 14 days a monoamine oxidase inhibitor (MAOI)
    c. **Additional for Daytrana and generic methylphenidate patch only:**
        i. Marked anxiety, tension, or agitation
        ii. Glaucoma
        iii. Tics or a family history or diagnosis of Tourette's syndrome

Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Aptensio XR, Azstarys, Cotempla XR-ODT, Daytrana, Jornay PM, methylphenidate ER or methylphenidate patch, Quillichew ER, Ritalin LA, and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist

2. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
    a. Achieved and maintains at least a 50% reduction from baseline in core symptoms of hyperactivity, impulsivity, and attention
    b. Achieved and maintains at least a 50% improvement from baseline in SKAMP rating scale
    c. Improved attention and social skills
    d. No aggressive behaviors

3. Individual has been adherent with the medication

4. **Additional criteria** for **brand Aptensio XR (methylphenidate hydrochloride extended release) capsule** : Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for the **generic methylphenidate hydrochloride ER capsule** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. **Additional criteria** for continuation of **Daytrana (methylphenidate) patch**: Individual has documented failure, contraindication per FDA label, or intolerance to the **generic methylphenidate patch** [Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. **If available:** Individual has documented failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use as follows:
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Development of psychotic or manic symptoms or other serious psychiatric events
        ii. Peripheral vasculopathy, including Raynaud's phenomenon
        iii. Priapism
        iv. Serious cardiovascular event such as stroke, or myocardial infarction
        v. **Additional for Daytrana and generic methylphenidate patch only:**
            1. Chemical leukoderma or signs of skin depigmentation
            2. Contact sensitization with erythema, edema, papules, & vesicles that has not improved within 48 hours or has spread beyond the patch site

8. There is 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)

9. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder

Renewal duration: 12 months

- 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**

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Generic Equivalent (if available)

Description:

Aptensio XR (methylphenidate), Azstarys (serdexmethylphenidate and dexmethylphenidate), 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 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, 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

o 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
- Difficulty with quiet activities
- "On the go"
- Excessive talking
- Blurting answers
- Can't wait turn
- Intrusive

o 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

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Generic Equivalent (if available)

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
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

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Generic Equivalent (if available)

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		
Atomoxatine (Strattera)	Cap	10, 18, 25, 40, 60, 80, 100 mg
Clonidine – central alpha-2 agonist		
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

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.

Azstarys (serdexmethylphenidate and dexmethylphenidate) capsule product information, revised by Corium, Inc. 10-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Cotempla XR-ODT (methylphenidate) orally disintegrating extended-release tablet product information, revised by Neos Therapeutics Brands, LLC. 06-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Daytrana (methylphenidate) patch product information, revised by Noven Therapeutics, LLC 11-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Jornay PM (methylphenidate) extended-release capsule product information, revised by Ironshore Pharmaceuticals, Inc. 10-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Methylphenidate extended-release capsule product information, revised by SpecGx LLC. 12-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Methylphenidate transdermal patch product information, revised by Padagis US LLC. 11-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Quillichew ER (methylphenidate) chewable extended-release tablet product information, revised by NextWave Pharmaceuticals, Inc. 10-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Ritalin LA (methylphenidate) extended-release capsule product information, revised by Novartis Pharmaceuticals Corporation. 10-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 17, 2025.

Chan E. Attention deficit hyperactivity disorder in children and adolescents: Overview of treatment and prognosis. In: UpToDate, Augustyn M, Tehrani N (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2025. Topic last updated June 25, 2024. Accessed April 14, 2025.

Chan E. Attention deficit hyperactivity disorder in children and adolescents: Treatment with medications. In: UpToDate, Augustyn M, Tehrani N (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2025. Topic last updated July 11, 2024. Accessed April 14, 2025.

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Brent D, Bukstein O, Solanto MV. Attention deficit hyperactivity disorder in adults: Treatment overview. In: UpToDate, Stein MB, Friedman M (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through March 2024. Topic last updated January 29, 2025. Accessed April 14, 2025.