BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**11/19/15**
LAST REVIEW DATE:	**11/15/18**
LAST CRITERIA REVISION DATE:	**11/15/18**
ARCHIVE DATE:	

APTENSIO XR™ (methylphenidate hydrochloride extended-release) oral capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Aptensio XR (methylphenidate hydrochloride extended-release) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 6 years of age or older

  2. A confirmed diagnosis of Attention Deficit Hyperactivity Disorder

  3. Individual has failure, contraindication or intolerance to **ALL** of the following preferred step therapy agents:
     - Preferred agents include:
       - Generic long acting methylphenidate:
         - Generic Concerta, generic Metadate CD and generic Ritalin LA
       - Vyvanse (lisdexamfetamine)
       - Adderall XR (Long acting mixed amphetamine salts)

  4. There are **NO** contraindications:
     - Contraindications include:
       - Use with a monoamine oxidase inhibitor (MAOI) or use of MAOI within the preceding 14 days
       - Hypersensitivity to methylphenidate

  5. There is no history of abuse of other stimulants

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

  7. There is no history of depressive symptoms or a family history of suicide, bipolar disorder, or depression

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Aptensio XR (methylphenidate hydrochloride extended-release) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     - Response is defined as:
       - Improved attention and social skills
       - Less hyperactivity, impulsivity, oppositional problems
       - No aggressive behaviors

  2. Individual has been adherent with the medication

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3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section
    - Significant adverse effect such as:
        - Hypersensitivity, angioedema, anaphylaxis
        - Cardiac abnormalities
        - Vascular disorder – Raynaud's phenomenon
        - Psychotic or manic symptoms

4. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Aptensio XR (methylphenidate) is a central nervous system stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Aptensio XR capsules contain multi layered beads, which are composed of an immediate-release layer which contains approximately 40% of the methylphenidate dose, and a controlled release layer which contains approximately 60% of the methylphenidate dose for once a day administration. The immediate release portion allows for the rapid development of plasma methylphenidate levels within 2 hours initially. The controlled release portion accounts for the development of a second rise in methylphenidate levels approximately 8 hours later with a gradual decline in methylphenidate levels throughout the day.

How Aptensio XR (methylphenidate) exerts its therapeutic benefit in the treatment of ADHD is unknown. Methylphenidate is a known central nervous system (CNS) stimulant. Methylphenidate is a racemic mixture of the d- and l-isomers. The d-isomer is more pharmacologically active than the l-isomer. Methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space. Methylphenidate is available in numerous formulations that includes short acting, intermediate acting, and long acting preparations. There are no studies that compare Aptensio XR directly with other long acting methylphenidate forms.

Attention Deficit Hyperactivity Disorder (ADHD)

- 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, and impulsivity that impair activities of daily living
- 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

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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 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
  - Side effects may occur with one type of stimulant but not another

- It is further suggested that if two or more first line stimulants are ineffective, non-stimulant medications may be added or used as mono-therapy
  - 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, or Guanfacine

- 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

Resources:

Aptensio XR. Package Insert. Revised by manufacturer 05/2015. Accessed 07/22/2015, 09/27/2016

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UpToDate: Attention deficit hyperactivity disorder in children and adolescents: Overview of treatment and prognosis. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-children-and-adolescents-overview-of-treatment-and-prognosis?source=search_result&search=adhd&selectedTitle=1~150

UpToDate: Attention deficit hyperactivity disorder in children and adolescents: Treatment with medications. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-children-and-adolescents-treatment-with-medications?source=search_result&search=adhd&selectedTitle=5~150

UpToDate: Attention deficit hyperactivity disorder in children and adolescents: Clinical features and diagnosis. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-children-and-adolescents-clinical-features-and-diagnosis?source=search_result&search=adhd&selectedTitle=4~150

UpToDate: Attention deficit hyperactivity disorder in adults: Epidemiology, pathogenesis, clinical features, course, assessment, and diagnosis. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-adults-epidemiology-pathogenesis-clinical-features-course-assessment-and-diagnosis?source=search_result&search=adhd&selectedTitle=2~150

UpToDate: Pharmacotherapy for adult attention deficit hyperactivity disorder. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/pharmacotherapy-for-adult-attention-deficit-hyperactivity-disorder?source=search_result&search=adhd&selectedTitle=3~150

UpToDate: Pharmacology of drugs used to treat attention deficit hyperactivity disorder in children and adolescents. Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/pharmacology-of-drugs-used-to-treat-attention-deficit-hyperactivity-disorder-in-children-and-adolescents?source=search_result&search=adhd&selectedTitle=7~150

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:		Dosage Form:
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.