BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 5/19/16**
SECTION: DRUGS	**LAST REVIEW DATE: 5/16/19**
	LAST CRITERIA REVISION DATE: 5/16/19
	ARCHIVE DATE:

DAYTRANA® (methylphenidate) transdermal patch

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:** Daytrana (methylphenidate transdermal system) 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 (ADHD)
  3. Individual has failure, intolerance or contraindication from a trial of immediate release methylphenidate product **or** immediate release dexmethylphenidate product
  4. Individual has failure, intolerance or contraindication from a trial of sustained release methylphenidate product **or** long acting dexmethylphenidate product
  5. Individual has failure, intolerance or contraindication from a trial of Adderall XR **or** a long acting dextroamphetamine product
  6. **ALL** of the following baseline tests have been completed before initiation of treatment:
     - Assessment for pre-existing cardiac disease
     - Assessment for risk of abuse
     - Assessment for pre-existing psychiatric disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder
  7. There are **NO** contraindications.
     - Contraindications include:
       - Known hypersensitivity to methylphenidate or other components of the product
       - Marked anxiety, tension, or agitation
       - Glaucoma
       - Tics or a family history or diagnosis of Tourette's syndrome
       - Individuals currently using or within 2 weeks of using an MAO inhibitor

  Initial approval duration: 6 months

- **Continuation of coverage (renewal request):** Daytrana (methylphenidate transdermal system) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition has not responded while on therapy
     - Response is defined as:
       - Adult and Child: Achieved and maintains at least a 50% reduction from baseline in core symptoms of hyperactivity, impulsivity, and attention
       - Child: Achieved and maintains at least a 50% improvement from baseline in SKAMP rating scale
  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:
        - Seizure
        - Development of psychotic or manic symptoms
        - Chemical leukoderma or signs of skin depigmentation
        - Contact sensitization with erythema, edema, papules, & vesicles that has not improved within 48 hours or has spread beyond the patch site

4. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Daytrana (methylphenidate) transdermal is a central nervous system stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Its mode of therapeutic action in ADHD is not known, but methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and to increase the release of these monoamines into the extraneuronal space.

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 (CNS) 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.

When one stimulant fails to manage the condition due to an inadequate response or intolerable adverse effects occur, it is suggested to change to another one of the first line stimulants within a different class. Approximately 50% of individuals not responding to one stimulant may respond to the other. It is further suggested that if two first line stimulants are ineffective, non-stimulant medications may be added or used as mono-therapy. Use of non-stimulant medications may also be beneficial in situations such as concerns about substance abuse or diversion, tic disorder, impulsivity, 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

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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.

Daytrana (methylphenidate) transdermal is an adhesive-based matrix transdermal system (patch) that contains methylphenidate in a multipolymeric adhesive and is applied to intact skin. The total dose delivered is dependent on the patch size and wear time. Methylphenidate is a racemic mixture comprised of the *d*-and *l*-enantiomers. The *d*-enantiomer is more pharmacologically active than the *l*-enantiomer.

Definitions:

ADHD medications – stimulants:

Methylphenidate-type products:		
Methylphenidate		
Aptensio XR	ER Cap 24 h	10, 15, 20, 30, 40, 50, 60 mg
Concerta	ER Tab	18, 27, 36, 54 mg
Daytrana	Transdermal	10 mg/9 hr, 15 mg/9 hr, 20 mg/9 hr, 30 mg/ 9 hr
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
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
Quillivant XR	ER Suspension	25 mg / 5 mL
Ritalin	Tab	5, 10, 20 mg
Ritalin LA	ER Cap 24 h	10, 20, 30, 40, 60 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

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Focalin	Tab	2.5, 5, 10 mg
Focalin XR	ER Cap 24 h	5, 10, 15, 20, 25, 30, 35, 40 mg
Listing does not imply formulary status or need for precertification 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
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		
Dexadrine	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
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 precertification or need step-therapy		

ADHD medications – non-stimulants:

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

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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 precertification or need step-therapy		

Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) rating scale:
The SKAMP rating scale is a validated 13-item teacher-rated scale that assesses manifestations of ADHD in a classroom setting. The SKAMP 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.

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

Resources:

Daytrana. Package Insert. Revised by manufacturer 08/2015. Accessed 04-21-2016.

Daytrana. Package Insert. Revised by manufacturer 01/2017. Accessed 04-08-2017.

Daytrana. Package Insert. Revised by manufacturer 11/2017. Accessed 03-14-2018, 04-17-2019

Daytrana product information accessed 05-02-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=2c312c31-3198-4775-91ab-294e0b4b9e7f

UpToDate: Attention deficit hyperactivity disorder in children and adolescents: Overview of treatment and prognosis. Current through Apr, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-children-and-adolescents-overview-of-treatment-and-prognosis?search=adhd&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H197690673

UpToDate: Attention deficit hyperactivity disorder in children and adolescents: Clinical features and diagnosis. Current through Apr, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-children-and-adolescents-clinical-features-and-diagnosis?search=adhd&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4

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UpToDate: Attention deficit hyperactivity disorder in children and adolescents: Treatment with medications. Current through Apr, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-children-and-adolescents-treatment-with-medications?search=adhd&source=search_result&selectedTitle=5~150&usage_type=default&display_rank=5

UpToDate: Attention deficit hyperactivity disorder in adults: Epidemiology, pathogenesis, clinical features, course, and diagnosis. Current through Apr, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/attention-deficit-hyperactivity-disorder-in-adults-epidemiology-pathogenesis-clinical-features-course-assessment-and-diagnosis?search=adhd&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

UpToDate: Pharmacotherapy for adult attention deficit hyperactivity disorder. Current through Apr, 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/pharmacotherapy-for-adult-attention-deficit-hyperactivity-disorder?search=adhd&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3

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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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Pharmacy Prior Authorization Request Form

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.