

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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## ADHD Narcolepsy

Override(s)	Approval Duration
Prior Authorization	1 year

*\*Indiana Medicaid – See State Specific Information Below*

*\*Maryland Medicaid – See State Specific Information Below*

*\*Washington Medicaid – See State Specific Information Below*

Medications
<b>Preferred Products</b>
<b><u>Atomoxetine:</u></b> Strattera generic
<b><u>Clonidine (extended release):</u></b> Kapvay generic
<b><u>Dexmethylphenidate:</u></b> Focalin generic Focalin XR generic
<b><u>Dextroamphetamine and Amphetamine:</u></b> Adderall generic Adderall XR generic
<b><u>Dextroamphetamine:</u></b> Dexedrine tablet generic Dexedrine capsules generic
<b><u>Methylphenidate:</u></b> Metadate ER generic methylphenidate products, except: chewable tablets and ER 72mg tablets
<b>Non-Preferred Products</b>
<b><u>Atomoxetine:</u></b> Strattera Brand
<b><u>Amphetamine:</u></b> Dyanavel XR Adzenys ER Suspension Adzenys XR-ODT

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<p><b><u>Clonidine (extended release):</u></b> Kapvay Brand</p>
<p><b><u>Guanfacine (extended release):</u></b> Intuniv and generic</p>
<p><b><u>Dextroamphetamine and Amphetamine:</u></b> Adderall Brand Adderall XR Brand Mydayis ER</p>
<p><b><u>Dextroamphetamine:</u></b> Dexedrine tablet Brand Dexedrine spansules Brand</p>
<p><b><u>Dexmethylphenidate:</u></b> Focalin Brand Focalin XR Brand</p>
<p><b><u>Transdermal Methylphenidate:</u></b> Daytrana</p>
<p><b><u>Dextroamphetamine:</u></b> ProCentra solution (and generic) Zenzedi</p>
<p><b><u>Methylphenidate:</u></b> Aptensio XR Concerta Brand Cotempla XR - ODT Metadate CD Brand Methylin Brand Methylin ER Brand Methylphenidate chewable tablets Methylphenidate ER 72mg tablets Relexxii ER 72mg tablets Ritalin Brand Ritalin LA Brand Ritalin SR Brand Quillichew ER Brand Quillivant XR Brand</p>

**\*\*\*Individuals age 19 and over will require prior authorization for diagnosis and trial of preferred products where applicable.\*\*\***

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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### **STEP THERAPY APPROVAL CRITERIA:**

Requests for a *non-preferred* ADHD agent [Dyanavel XR, Adenzys XR-ODT, Adzenys ER Suspension, Kapvay (brand) , Intuniv (brand and generic), Adderall (brand), Adderall XR (brand), Mydayis ER, Dexedrine tablet (brand), Dexedrine Spansules (brand), Focalin (brand), Focalin XR (brand), Daytrana, Procentra solution (and generic), Zenzedi, Aptensio XR, Concerta (brand), Cotempla XR-ODT, Metadate CD (brand), Methylin (brand), Methylin ER (brand), methylphenidate chewable tablets, methylphenidate ER 72mg tablets, Ritalin (brand), Ritalin LA (brand), Ritalin SR (brand), Quillichew ER, Quillivant XR, Relexxii ER 72mg tablets (brand), Strattera (brand)] may be approved if the following step therapy criteria are met **in addition to** any prior authorization criteria listed below:

- I. Individual has been on requested non-preferred ADHD agent in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial); **OR**
- II. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred agent;

**Preferred agents:** atomoxetine, clonidine extended-release, dexamethylphenidate (IR and XR), dextroamphetamine-amphetamine tablet (IR and ER), dextroamphetamine tablet, dextroamphetamine SR capsules, the following generic methylphenidate agents: [methylphenidate ER (not 72mg)/SR/CR tablet, methylphenidate tablet/oral solution, methylphenidate ER 24-hr tablet (AB-rated generic Concerta), methylphenidate CD/ER/LA capsule], Metadate ER.

**OR**

- III. The preferred agents are not FDA-approved for the prescribed indication and do not have an accepted off-label use per the off-label policy for the prescribed indication and the requested non-preferred agent does; **OR**
- IV. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to the following:
  - A. Individual's age: **OR**
  - B. Other known disease state or medication contraindication which is not also associated with the requested non-preferred agent.

### **PRIOR AUTHORIZATION APPROVAL CRITERIA:**

- I. **Dexamethylphenidate (Focalin and generic, Focalin XR and generic), Amphetamine (Dyanavel XR, Adzenys XR-ODT, Adzenys ER Suspension), Guanfacine extended release (Intuniv and generic), Clonidine extended release (Kapvay and generic), Atomoxetine (Strattera and generic):**

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.  
CRX-ALL-0259-18

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Approve Dexmethylphenidate (Focalin and generic, Focalin XR and generic), Amphetamine (Dyanavel XR, Adzenys XR-ODT, Adzenys ER Suspension), and Guanfacine extended release (Intuniv and generic), Clonidine extended release (Kapvay and generic), and Atomoxetine (Strattera and generic) when the following FDA approved indications or medically accepted usage criteria is met, if required by benefit:

- A. Individual is 6 years of age or older; **AND**
- B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD).

**Note:** Focalin and Focalin XR (dexmethylphenidate) have a black box warning for the potential of drug dependence. Focalin and Focalin XR should be given cautiously to individuals with a history of drug dependence or alcoholism. Chronic abuse can lead to marked tolerance and psychological dependence. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

II. **Transdermal Methylphenidate (Daytrana):**

Approve Transdermal Methylphenidate (Daytrana) when the following FDA approved indications or medically accepted usage criteria is met, if required by benefit:

- A. Individual is 6 years of age or older; **AND**
- B. Individual has a diagnosis of attention deficit hyperactivity disorder; **AND**
- C. Individual has had a suboptimal response to **one** maximally titrated long-acting methylphenidate product; **OR**
- D. Individual has experienced **one** of the following adverse effects on previous therapy:
  1. Diminished appetite and documented weight loss from baseline over a three (3) month observation period; **OR**
  2. An elevated blood pressure over baseline demonstrated by at least three measurements over one (1) week period; **OR**
  3. Behavior or mood changes interfering with daily activities, including complaints of abdominal distress, sleep problems, or oppositional/rebellious/aggressive behavior.

**Note:** Methylphenidate products have a black box warning for the potential for abuse and dependence. Methylphenidate containing products should be given cautiously to individuals with a history of drug dependence or alcoholism. Chronic abuse can lead to marked tolerance and psychological dependence. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up. The risk of abuse prior to prescribing should be assessed and the individual monitored for signs of abuse and dependence while on therapy.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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**III. Dextroamphetamine (Dexedrine, Dexedrine Spansules, ProCentra solution (and generic), Zenzedi and generic products):**

A. Individual has been on requested preferred ADHD agent in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial);

**OR**

B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**

C. One of the following:

1. Individual is 3 years of age or older and using immediate-release product;

**OR**

2. Individual is 6 years of age or older and using an extended-release product;

**OR**

D. Individual is 6 years of age or older; **AND**

E. Individual has a diagnosis of narcolepsy.

**Note:** Amphetamine products have a black box warning for a potential for abuse. Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependence. Special attention should be made to the possibility of non-therapeutic use or distribution to others. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions.

**IV. Dextroamphetamine and Amphetamine (Adderall, Adderall XR and generic products):**

A. Individual has been on requested preferred ADHD agent in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial);

**OR**

B. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**

C. One of the following:

1. Individual is 3 years of age or older and using an immediate-release product;

**OR**

2. Individual is 6 years of age or older and using an extended-release product;

**OR**

D. Individual is 6 years of age or older; **AND**

E. Individual is using an immediate-release product for the treatment of narcolepsy.

**Note:** Amphetamine products have a black box warning for a potential for abuse. Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependence. Special attention should be made to the possibility of non-therapeutic use or distribution to others. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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V. **Dextroamphetamine and Amphetamine (Mydayis ER products):**

- A. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**
- B. Individual is 13 years of age or older.

**Note:** Amphetamine products have a black box warning for a potential for abuse. Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependence. Special attention should be made to the possibility of non-therapeutic use or distribution to others. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions.

VI. **Methylphenidate (Methylin, Methylin ER, Ritalin, Ritalin SR and generic products (not methylphenidate ER 72mg tablets):**

- A. Individual has been on requested preferred ADHD agent in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial);

**OR**

- B. Individual is 6 years of age or older; **AND**
- C. One of the following:

- 1. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **OR**
- 2. Individual has a diagnosis of narcolepsy.

**OR**

- D. Individual is 4 or 5 years of age; **AND**
- E. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**
- F. Individual and caregivers have participated in behavioral interventions; **AND**
- G. Individual continues with moderate-to-severe disturbance in function. (AAP 2011).

**Note:** Methylphenidate products have a black box warning for the potential for abuse and dependence. Methylphenidate containing products should be given cautiously to individuals with a history of drug dependence or alcoholism. Chronic abuse can lead to marked tolerance and psychological dependence. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up. The risk of abuse prior to prescribing should be assessed and the individual monitored for signs of abuse and dependence while on therapy.

VII. **Methylphenidate (Aptensio XR, Cotempla XR-ODT, Concerta, Metadate CD, Metadate ER, methylphenidate ER 72mg tablets, Relexxii ER 72mg tablets, Quillichew ER, Quillivant XR, Ritalin LA and generic products):**

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A. Individual has been on requested preferred ADHD agent in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial);

**OR**

B. Individual is 6 years of age or older; **AND**

C. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD);

**OR**

D. Individual is 4 or 5 years of age; **AND**

E. Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD); **AND**

F. Individual and caregivers have participated in behavioral interventions; **AND**

G. Individual continues with moderate-to-severe disturbance in function. (AAP 2011)

**Note:** Methylphenidate products have a black box warning for the potential for abuse and dependence. Methylphenidate containing products should be given cautiously to individuals with a history of drug dependence or alcoholism. Chronic abuse can lead to marked tolerance and psychological dependence. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up. The risk of abuse prior to prescribing should be assessed and the individual monitored for signs of abuse and dependence while on therapy.

Note: Attention deficit hyperactivity disorder (ADHD) may also be referred to as attention deficit disorder (ADD). State benefit mandates may apply for continued use into adulthood. Prior authorization may be required.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Indiana		Age limits on ADHD medications apply. If prior authorization is required, request will be reviewed on a case by case basis.
Maryland		<ul style="list-style-type: none"> <li>Behavioral health carved out in Maryland; however, pharmacy coverage is provided for the following agents and above criteria will be applied: <ul style="list-style-type: none"> <li>Kapvay (and generic)</li> <li>Intuniv (and generic)</li> </ul> </li> </ul>

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Washington		<ul style="list-style-type: none"> <li>• No Quantity Limits, duplication of therapy or duration will apply for adults 18 years of age and older</li> <li>• Provide indefinite coverage for members 21 years of age and younger ONLY IF PREVIOUSLY PRESCRIBED</li> <li>o If the member comes to us on the ADHD therapy, they can remain on that therapy regardless of formulary status (would need to have been on the same medication for 30 days within the past 90 days)</li> </ul>
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**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.