

# PRIOR AUTHORIZATION CRITERIA

| <b>DRUG CLASS</b>               | <b>ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) AGENTS</b>                               |
|---------------------------------|---|
| <b>BRAND NAME<br/>(generic)</b> | <b>ADDERALL<br/>(amphetamine mixture)</b>   |
|                                 | <b>ADDERALL XR<br/>(amphetamine extended-release mixture)</b>                               |
|                                 | <b>ADZENYS ER<br/>(amphetamine extended-release oral suspension)</b>                        |
|                                 | <b>ADZENYS XR-ODT<br/>(amphetamine extended-release orally disintegrating tablets)</b>      |
|                                 | <b>APTENSIO XR<br/>(methylphenidate extended-release)</b>                                   |
|                                 | <b>CONCERTA<br/>(methylphenidate extended-release)</b>                                      |
|                                 | <b>COTEMPLA XR-ODT<br/>(methylphenidate extended-release orally disintegrating tablets)</b> |
|                                 | <b>DAYTRANA<br/>(methylphenidate transdermal system)</b>                                    |
|                                 | <b>DESOXYN<br/>(methamphetamine)</b>  |
|                                 | <b>DEXTROAMPHETAMINE PRODUCTS<br/>(dextroamphetamine)</b>                                   |
|                                 | <b>DEXEDRINE SPANSULE<br/>(dextroamphetamine sustained-release)</b>                         |
|                                 | <b>DYANAVAL XR<br/>(amphetamine extended-release oral suspension)</b>                       |
|                                 | <b>EVEKEO<br/>(amphetamine sulfate)</b>   |
|                                 | <b>FOCALIN<br/>(dexamethylphenidate)</b>  |

**FOCALIN XR**  
(dexmethylphenidate extended-release)

**METADATE CD**  
(methylphenidate extended-release)

**METHYLIN CHEWABLE TABLET**  
(methylphenidate chewable tablet)

**methylphenidate tablets**

**methylphenidate oral solution**

**methylphenidate extended-release products**

**MYDAYIS**  
(amphetamine mixture extended-release)

**PROCENTRA**  
(dextroamphetamine sulfate oral solution)

**QUILLICHEW ER**  
(methylphenidate extended-release chewable tablets)

**QUILLIVANT XR**  
(methylphenidate hydrochloride extended-release oral suspension)

**RITALIN LA**  
(methylphenidate extended-release)

**STRATTERA**  
(atomoxetine)

**VYVANSE**  
(lisdexamfetamine)

**ZENZEDI**  
(dextroamphetamine)

**Status: CVS Caremark Criteria**

**Type: Post Limit Prior Authorization**

## **POLICY**

## **FDA-APPROVED INDICATIONS**

### **Adderall**

Adderall is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

### **Adderall XR**

Adderall XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

### **Adzenys ER**

Adzenys ER is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

### **Adzenys XR-ODT**

Adzenys XR-ODT is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

### **Aptensio XR**

Aptensio XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

### **Concerta**

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.

### **Cotempla XR-ODT**

Cotempla XR-ODT is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

### **Daytrana**

Daytrana is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

### **Desoxyn**

Desoxyn is indicated for Attention Deficit Disorder with Hyperactivity and Exogenous Obesity.

### **Dexedrine Spansule**

Dexedrine Spansules are indicated for the treatment of Narcolepsy and Attention Deficit Disorder with Hyperactivity.

### **Dextroamphetamine**

Dextroamphetamine is indicated for the treatment of Narcolepsy and Attention Deficit Disorder with Hyperactivity.

### **Dyanavel XR**

Dyanavel XR is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

### **Evekeo**

Evekeo is indicated for Narcolepsy, Attention Deficit Disorder with Hyperactivity, and Exogenous Obesity.

### **Focalin**

Focalin is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

### **Focalin XR**

Focalin XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients aged six years and older.

### **Metadate CD**

Metadate CD is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

### **Methylin Chewable Tablets**

Methylphenidate Chewable Tablets are indicated for Attention Deficit Disorders and Narcolepsy.

**Methylphenidate/Methylphenidate Extended-release**

Methylphenidate and methylphenidate extended-release are indicated for Attention Deficit Disorders and Narcolepsy.

**Mydayis**

Mydayis is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13 years and older.

**ProCentra**

ProCentra is indicated for the treatment of Narcolepsy and Attention Deficit Disorder with Hyperactivity.

**QuilliChew ER**

QuilliChew ER is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**Quillivant XR**

Quillivant XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**Ritalin LA**

Ritalin LA is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**Strattera**

Strattera is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

**Vyvanse**

Vyvanse is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and moderate to severe Binge-Eating Disorder (BED).

**Zenzedi**

Zenzedi is indicated for Narcolepsy and Attention Deficit Disorder with Hyperactivity.

**For all ADHD Agents:**

Attention Deficit Hyperactivity Disorder (ADHD)

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD; DSM-V) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and be present in two or more settings, e.g., school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the Inattentive Type, at least six 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. For the Hyperactive-Impulsive Type, at least six 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. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

**COVERAGE CRITERIA**

- ADHD/Narcolepsy Agents will be covered with prior authorization when the following criteria are met:
  - The patient has a diagnosis of Attention-Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) **AND**
  - The diagnosis has been appropriately documented (i.e., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires).

**OR**

- The patient has a diagnosis of narcolepsy confirmed by a sleep study **AND**
- This request is NOT for amphetamine extended-release mixture (Adderall XR, Mydayis), amphetamine extended-release (Adzenys ER, Adzenys XR-ODT), methylphenidate immediate release, methylphenidate extended-release (Aptensio XR, Concerta, Cotempla XR, Metadate CD, QuilliChew ER,

Quillivant XR, Ritalin LA), dexamethylphenidate (Focalin), dexamethylphenidate extended-release (Focalin XR) or methylphenidate chewable tablet (Methylin chewable tablet)

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| <b>Quantity for Approval - Quantity Chart for ADHD**</b> |                          |                          |
|--|--------------------------|--------------------------|
| <b>Drug</b>  | <b>Quantity/25 days*</b> | <b>Quantity/75 days*</b> |
| Adderall 5 mg, 7.5 mg, 10 mg, 12.5 mg                    | 120 tablets              | 360 tablets              |
| Adderall 15 mg, 20 mg                                    | 90 tablets               | 270 tablets              |
| Adderall 30 mg   | 60 tablets               | 180 tablets              |

|  |              |              |
|--|--------------|--------------|
| Adderall XR 5 mg, 10 mg                              | 120 capsules | 360 capsules |
| Adderall XR 15 mg, 20 mg, 25 mg, 30 mg               | 60 capsules  | 180 capsules |
| Adzenys ER oral suspension 1.25 mg/ml                | 900 ml       | 2700 ml      |
| Adzenys XR-ODT 3.1 mg, 6.3 mg, 9.4 mg                | 120 tablets  | 360 tablets  |
| Adzenys XR-ODT 12.5 mg, 15.7 mg, 18.8 mg             | 60 capsules  | 180 capsules |
| Aptensio XR 10 mg, 15 mg, 20 mg, 30 mg               | 90 capsules  | 270 capsules |
| Aptensio XR 40 mg, 50 mg                             | 60 capsules  | 180 capsules |
| Concerta 18 mg, 27 mg, 36 mg                         | 90 tablets   | 270 tablets  |
| Concerta 54 mg                                       | 60 tablets   | 180 tablets  |
| Cotempla XR 8.6 mg, 17.3 mg                          | 120 tablets  | 360 tablets  |
| Cotempla XR 25.9 mg                                  | 90 tablets   | 270 tablets  |
| Dextroamphetamine 2.5 mg, 5 mg, 7.5 mg, 10 mg        | 180 tablets  | 540 tablets  |
| Dextroamphetamine 15 mg                              | 120 tablets  | 360 tablets  |
| Dextroamphetamine 20 mg                              | 90 tablets   | 270 tablets  |
| Dextroamphetamine 30 mg                              | 60 tablets   | 180 tablets  |
| Dexedrine Spansule 5 mg, 10 mg                       | 150 capsules | 450 capsules |
| Dexedrine Spansule 15 mg                             | 120 capsules | 360 capsules |
| Evekeo 5 mg, 10 mg                                   | 180 tablets  | 540 tablets  |
| Focalin 2.5 mg, 5 mg, 10 mg                          | 150 tablets  | 450 tablets  |
| Focalin XR 5 mg, 10 mg, 15 mg                        | 90 capsules  | 270 capsules |
| Focalin XR 20 mg, 25 mg                              | 60 capsules  | 180 capsules |
| Metadate CD 10 mg, 20 mg, 30 mg                      | 90 capsules  | 270 capsules |
| Metadate CD 40 mg, 50 mg                             | 60 capsules  | 180 capsules |
| Methylin chewable tablets 2.5 mg, 5 mg, 10 mg        | 300 tablets  | 900 tablets  |
| Methylphenidate 5 mg, 10 mg                          | 210 tablets  | 630 tablets  |
| Methylphenidate 20 mg                                | 150 tablets  | 450 tablets  |
| Methylphenidate oral solution 5 mg/5 ml              | 3,000 ml     | 9,000 ml     |
| Methylphenidate oral solution 10mg/5ml               | 1,500 ml     | 4,500 ml     |
| Methylphenidate ER 10 mg, 20 mg                      | 150 tablets  | 450 tablets  |
| Mydayis 12.5 mg                                      | 90 capsules  | 270 capsules |
| Mydayis 25 mg  | 60 capsules  | 180 capsules |
| Mydayis 37.5 mg, 50 mg                               | 30 capsules  | 90 capsules  |
| ProCentra oral solution 5mg/5ml                      | 1,800 ml     | 5,400 ml     |
| QuilliChew ER 20 mg                                  | 150 tablets  | 450 tablets  |
| QuilliChew ER 30 mg                                  | 90 tablets   | 270 tablets  |
| QuilliChew ER 40 mg                                  | 60 tablets   | 180 tablets  |
| Quillivant XR oral suspension 25 mg/5 mL (5 mg/1 ml) | 600 ml       | 1,800 ml     |
| Ritalin LA 10 mg, 20 mg                              | 150 capsules | 450 capsules |
| Ritalin LA 30 mg                                     | 90 capsules  | 270 capsules |
| Ritalin LA 40 mg                                     | 60 capsules  | 180 capsules |
| Zenedi 2.5 mg, 5 mg, 7.5 mg, 10 mg                   | 180 tablets  | 540 tablets  |
| Zenedi 15 mg   | 120 tablets  | 360 tablets  |
| Zenedi 20 mg   | 90 tablets   | 270 tablets  |
| Zenedi 30 mg   | 60 tablets   | 180 tablets  |

*\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

\*\*The initial limits for Aptensio XR 60 mg, Daytrana, Desoxyn, Dyanavel XR, Focalin XR 30 mg, 35 mg, and 40 mg, Metadate CD 60 mg, Mydayis 25 mg, 37.5 mg, 50 mg, Ritalin LA 60 mg, Strattera, and Vyvanse are set at the off-label maximum daily dose for ADHD; therefore, no post limit quantities will be available for these drugs for the diagnosis of ADHD.

| <b>Quantity for Approval - Quantity Chart for Narcolepsy**</b> |                          |                          |
|--|--------------------------|--------------------------|
| <b>Drug</b>  | <b>Quantity/25 days*</b> | <b>Quantity/75 days*</b> |
| Adderall 5 mg, 7.5 mg, 10 mg, 12.5 mg                          | 120 tablets              | 360 tablets              |
| Adderall 15 mg, 20 mg  | 90 tablets               | 270 tablets              |
| Adderall 30 mg   | 60 tablets               | 180 tablets              |
| Dextroamphetamine 2.5 mg, 5 mg, 7.5 mg, 10 mg                  | 180 tablets              | 540 tablets              |
| Dextroamphetamine 15 mg  | 120 tablets              | 360 tablets              |
| Dextroamphetamine 20 mg  | 90 tablets               | 270 tablets              |
| Dextroamphetamine 30 mg  | 60 tablets               | 180 tablets              |
| Dexedrine Spansule 5 mg, 10 mg                                 | 150 capsules             | 450 capsules             |
| Dexedrine Spansule 15 mg                                       | 120 capsules             | 360 capsules             |
| Evekeo 5 mg, 10 mg   | 180 tablets              | 540 tablets              |
| ProCentra oral solution 5mg/5ml                                | 1,800 ml                 | 5,400 ml                 |
| Zenzedi 2.5 mg, 5 mg, 7.5 mg, 10 mg                            | 180 tablets              | 540 tablets              |
| Zenzedi 15 mg  | 120 tablets              | 360 tablets              |
| Zenzedi 20 mg  | 90 tablets               | 270 tablets              |
| Zenzedi 30 mg  | 60 tablets               | 180 tablets              |

*\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*

\*\*The initial limits for methylphenidate, methylphenidate extended-release, and Methylin chewable tablets are set at the FDA maximum approved daily doses for narcolepsy; therefore, no post limit quantities will be available for these drugs for the diagnosis of narcolepsy.