CVS Caremark®

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| Reference number(s) |
| 1218-J, 683-J |

# Post Limit Prior Authorization Attention Deficit Hyperactivity Disorder (ADHD) Agents

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

### Amphetamines

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Adzenys | amphetamine | all products |
| Dyanavel | amphetamine | all products |
| Evekeo | amphetamine | all products |

### Amphetamine-Dextroamphetamines

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Adderall | amphetamine-dextroamphetamine | all products |
| Mydayis | amphetamine-dextroamphetamine | all products |

### Dexmethylphenidates

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Azstarys | serdexmethylphenidate / dexmethylphenidate | all products |
| Focalin | dexmethylphenidate | all products |

### Dextroamphetamines

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Dexedrine | dextroamphetamine | all products |
| dextroamphetamine (all other brands) | dextroamphetamine | all products |
| ProCentra | dextroamphetamine | all products |
| Xelstrym | dextroamphetamine | all products |
| Zenzedi | dextroamphetamine | all products |

### Lisdexamfetamines

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Arynta | lisdexamfetamine | all products |
| Vyvanse | lisdexamfetamine | all products |

### Methamphetamines

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Desoxyn | methamphetamine | all products |

### Methylphenidates

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Aptensio | methylphenidate | all products |
| Concerta | methylphenidate | all products |
| Cotempla | methylphenidate | all products |
| Daytrana | methylphenidate | all products |
| Jornay | methylphenidate | all products |
| Metadate | methylphenidate | all products |
| Methylin | methylphenidate | all products |
| methylphenidate (all other brands) | methylphenidate | all products |
| QuilliChew | methylphenidate | all products |
| Quillivant | methylphenidate | all products |
| Relexxii | methylphenidate | all products |
| Ritalin | methylphenidate | all products |

### Selective Norepinephrine Reuptake Inhibitors

| Brand Name | Generic Name | Dosage Form |
| --- | --- | --- |
| Qelbree | viloxazine | all products |
| Strattera | atomoxetine | all products |

## Indications

### FDA-approved Indications

#### Adderall

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

#### Adderall XR, Qelbree

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

#### Adzenys XR-ODT, Azstarys, Dyanavel XR, Jornay PM

These products are 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) in patients 6 years and older.

##### Limitations of Use:

Pediatric patients younger than 6 years of age experienced higher plasma exposure than patients 6 years and older at the same dose and high rates of adverse reactions, most notably weight loss.

#### Arynta, Vyvanse

These products are indicated for the treatment of:

* Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older
* Moderate to severe binge-eating disorder (BED) in adults

##### Limitations of Use:

* Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
* These products are not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of these products for the treatment of obesity have not been established.

#### 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, Daytrana, Evekeo ODT

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

#### Desoxyn

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

#### Dexedrine Spansule

Dexedrine is indicated in:

Narcolepsy

Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program that typically includes other measures (psychological, educational, social) for patients (ages 6 years to 16 years) with this syndrome.

#### Dextroamphetamine Sulfate Tablets, ProCentra, Zenzedi

Dextroamphetamine Sulfate is indicated for:

* Narcolepsy.
* Attention Deficit Disorder with Hyperactivity, as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 to 16 years) with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

#### Evekeo

Evekeo (amphetamine sulfate tablets, USP) is indicated for:

* Narcolepsy
* Attention Deficit Disorder with Hyperactivity as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.
* Exogenous Obesityas a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs. The limited usefulness of amphetamines should be weighed against possible risks inherent in use of the drug.

#### Focalin, Focalin XR, QuilliChew ER, Quillivant XR

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

#### Metadate CD

Metadate CD is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 15 years of age.

#### Methylin Oral Solution

Methylin is indicated for the treatment of:

* Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older
* Narcolepsy

#### Methylphenidate Chewable Tablets

Attention Deficit Disorders

Methylphenidate hydrochloride chewable tablets are indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

Narcolepsy

#### Methylphenidate Extended-Release, Ritalin

These products are indicated for the treatment of:

* Attention Deficit Hyperactivity Disorders (ADHD) in pediatric patients 6 years and older and adults
* Narcolepsy

#### Methylphenidate LA, Ritalin LA

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD), in pediatric patients 6 to 12 years of age.

#### Methylphenidate Osmotic Extended-Release, Relexxii

These products are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older.

#### Mydayis

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

##### Limitations of Use:

Pediatric patients 12 years and younger experienced higher plasma exposure than patients 13 years and older at the same dose, and experienced higher rates of adverse reactions, mainly insomnia and decreased appetite.

#### Strattera

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

The efficacy of Strattera capsules was established in seven clinical trials in outpatients with ADHD; four 6 to 9-week trials in pediatric patients (ages 6 to 18), two 10-week trials in adults, and one maintenance trial in pediatrics (ages 6 to 15).

#### Xelstrym

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

##### Limitations of Use:

Pediatric patients younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.

## Coverage Criteria

### Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

* The diagnosis has been appropriately documented (e.g., evaluated by a complete clinical assessment, using DSM-5, standardized rating scales, interviews/questionnaires).
* If the patient is 5 years of age or younger, the patient continues to have ADHD/ADD symptoms despite participating in evidence-based behavioral therapy (e.g., parent training in behavior management (PTBM), behavioral classroom interventions).

### Narcolepsy

Authorization may be granted when the patient has a diagnosis of narcolepsy when ALL of the following criteria are met:

* This request is NOT for amphetamine extended-release (Adzenys ER, Adzenys XR-ODT), amphetamine-dextroamphetamine extended-release (Adderall XR), amphetamine sulfate orally disintegrating tablet (Evekeo ODT), methylphenidate chewable tablet, methylphenidate immediate release, methylphenidate extended-release (Aptensio XR, Concerta, Cotempla XR-ODT, methylphenidate CD, Methylphenidate Osmotic Extended-Release, Relexxii, Ritalin LA), dexmethylphenidate (Focalin), or dexmethylphenidate extended-release (Focalin XR).
* The requested drug is being prescribed by, or in consultation with, a sleep specialist.
* The diagnosis has been confirmed by a sleep study.

## Continuation of Therapy

### Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD)

Authorization may be granted when the patient has a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) when ALL of the following criteria are met:

* The patient achieved or maintained improvement in their signs and symptoms of ADHD/ADD from baseline.
* The patient’s need for continued therapy has been assessed within the previous year.

### Narcolepsy

Authorization may be granted when the patient has a diagnosis of narcolepsy when ALL of the following criteria are met:

* This request is NOT for amphetamine extended-release (Adzenys ER, Adzenys XR-ODT), amphetamine-dextroamphetamine extended-release (Adderall XR), amphetamine sulfate orally disintegrating tablet (Evekeo ODT), methylphenidate chewable tablet, methylphenidate immediate release, methylphenidate extended-release (Aptensio XR, Concerta, Cotempla XR-ODT, methylphenidate CD, Methylphenidate Osmotic Extended-Release, Relexxii, Ritalin LA), dexmethylphenidate (Focalin), or dexmethylphenidate extended-release (Focalin XR).
* The patient has achieved or maintained improvement in daytime sleepiness with narcolepsy from baseline.

## Quantity Limits Apply

### Post Limit Quantity for ADHD

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.

Aptensio XR 60 mg; Focalin XR 20 mg, 30 mg, 35 mg, and 40 mg; Metadate CD 60 mg; Methylphenidate LA 60 mg; Methylphenidate Osmotic Extended-Release 63 mg and 72 mg; and Relexxii 63 mg and 72 mg, strengths are not included in the post limit because a quantity that is greater than the initial limit would result in exceeding the off-label maximum daily dose.

The initial limits for Arynta, Azstarys, Daytrana, Desoxyn, Dyanavel XR, Jornay PM, Mydayis, Qelbree, QuilliChew ER, Quillivant XR, Strattera, Vyvanse, and Xelstrym are set at the off-label maximum daily dose for ADHD or there is no established off-label maximum daily dosage; therefore, no post limit quantities will be available for these drugs for the diagnosis of ADHD.

| **Drug** | **Quantity / 25 days** | **Quantity / 75 days** |
| --- | --- | --- |
| Adderall (amphetamine-dextroamphetamine) 5 mg, 7.5 mg, 10 mg, 12.5 mg | 120 tablets | 360 tablets |
| Adderall (amphetamine-dextroamphetamine) 15 mg, 20 mg | 90 tablets | 270 tablets |
| Adderall (amphetamine-dextroamphetamine) 30 mg | 60 tablets | 180 tablets |
| Adderall XR (amphetamine-dextroamphetamine extended-release) 5 mg, 10 mg | 120 capsules | 360 capsules |
| Adderall XR (amphetamine-dextroamphetamine extended-release) 15 mg, 20 mg, 25 mg, 30 mg | 60 capsules | 180 capsules |
| 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 tablets | 180 tablets |
| Aptensio XR (methylphenidate extended-release) 10 mg, 15 mg, 20 mg, 30 mg | 90 capsules | 270 capsules |
| Aptensio XR (methylphenidate extended-release) 40 mg, 50 mg | 60 capsules | 180 capsules |
| Concerta (methylphenidate osmotic extended-release) 18 mg, 27 mg, 36 mg | 90 tablets | 270 tablets |
| Concerta (methylphenidate osmotic extended-release) 54 mg | 60 tablets | 180 tablets |
| Cotempla XR-ODT 8.6 mg, 17.3 mg | 120 tablets | 360 tablets |
| Cotempla XR-ODT 25.9 mg | 90 tablets | 270 tablets |
| Dexedrine Spansule (dextroamphetamine sustained-release) 10 mg | 150 capsules | 450 capsules |
| Dexedrine Spansule (dextroamphetamine sustained-release) 15 mg | 120 capsules | 360 capsules |
| Dextroamphetamine extended-release 5 mg | 150 capsules | 450 capsules |
| Dextroamphetamine 5 mg, 10 mg | 180 tablets | 540 tablets |
| Evekeo (amphetamine) 5 mg, 10 mg | 180 tablets | 540 tablets |
| Evekeo ODT 5 mg, 10 mg | 180 tablets | 540 tablets |
| Evekeo ODT 15 mg, 20 mg | 90 tablets | 270 tablets |
| Focalin (dexmethylphenidate) 2.5 mg, 5 mg, 10 mg | 150 tablets | 450 tablets |
| Focalin XR (dexmethylphenidate extended-release) 5 mg, 10 mg, 15 mg | 90 capsules | 270 capsules |
| Focalin XR (dexmethylphenidate extended-release) 25 mg | 60 capsules | 180 capsules |
| Metadate (methylphenidate extended-release [CD]) 10 mg, 20 mg, 30 mg | 90 capsules | 270 capsules |
| Metadate (methylphenidate extended-release [CD]) 40 mg, 50 mg | 60 capsules | 180 capsules |
| Methylin (methylphenidate) oral solution 5 mg / 5 mL | 3,000 mL | 9,000 mL |
| Methylin (methylphenidate) oral solution 10 mg / 5 mL | 1,500 mL | 4,500 mL |
| Methylphenidate chewable tablets 2.5 mg, 5 mg, 10 mg | 300 tablets | 900 tablets |
| Methylphenidate extended-release 10 mg, 20 mg | 150 tablets | 450 tablets |
| Methylphenidate Osmotic Extended-Release 45 mg | 60 tablets | 180 tablets |
| ProCentra (dextroamphetamine) oral solution 5 mg / 5 mL | 1,800 mL | 5,400 mL |
| Relexxii (methylphenidate osmotic extended-release) 18 mg, 27 mg, 36 mg | 90 tablets | 270 tablets |
| Relexxii 45 mg | 60 tablets | 180 tablets |
| Relexxii (methylphenidate osmotic extended-release) 54 mg | 60 tablets | 180 tablets |
| Ritalin (methylphenidate) 5 mg, 10 mg | 210 tablets | 630 tablets |
| Ritalin (methylphenidate) 20 mg | 150 tablets | 450 tablets |
| Ritalin LA (methylphenidate extended-release (LA)) 10 mg, 20 mg | 150 capsules | 450 capsules |
| Ritalin LA (methylphenidate extended-release (LA)) 30 mg | 90 capsules | 270 capsules |
| Ritalin LA (methylphenidate extended-release (LA)) 40 mg | 60 capsules | 180 capsules |
| Zenzedi (dextroamphetamine) 2.5 mg, 5 mg, 7.5 mg, 10 mg | 180 tablets | 540 tablets |
| Zenzedi (dextroamphetamine) 15 mg | 120 tablets | 360 tablets |
| Zenzedi (dextroamphetamine) 20 mg | 90 tablets | 270 tablets |
| Zenzedi (dextroamphetamine) 30 mg | 60 tablets | 180 tablets |

### Post Limit Quantity for Narcolepsy

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 immediate-release, methylphenidate extended-release, and methylphenidate 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.

| **Drug** | **Quantity / 25 days** | **Quantity / 75 days** |
| --- | --- | --- |
| Adderall (amphetamine-dextroamphetamine) 5 mg, 7.5 mg, 10 mg, 12.5 mg | 120 tablets | 360 tablets |
| Adderall (amphetamine-dextroamphetamine) 15 mg, 20 mg | 90 tablets | 270 tablets |
| Adderall (amphetamine-dextroamphetamine) 30 mg | 60 tablets | 180 tablets |
| Dexedrine Spansule (dextroamphetamine sustained-release) 10 mg | 150 capsules | 450 capsules |
| Dexedrine Spansule (dextroamphetamine sustained-release) 15 mg | 120 capsules | 360 capsules |
| Dextroamphetamine extended-release 5 mg | 150 capsules | 450 capsules |
| Dextroamphetamine 5 mg, 10 mg | 180 tablets | 540 tablets |
| Evekeo (amphetamine) 5 mg, 10 mg | 180 tablets | 540 tablets |
| ProCentra (dextroamphetamine) oral solution 5 mg / 5 mL | 1,800 mL | 5,400 mL |
| Zenzedi (dextroamphetamine) 2.5 mg, 5 mg, 7.5 mg, 10 mg | 180 tablets | 540 tablets |
| Zenzedi (dextroamphetamine) 15 mg | 120 tablets | 360 tablets |
| Zenzedi (dextroamphetamine) 20 mg | 90 tablets | 270 tablets |
| Zenzedi (dextroamphetamine) 30 mg | 60 tablets | 180 tablets |

## Duration of Approval (DOA):

* 1218-J: DOA: 36 months
* 683-J: DOA: 12 months

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