

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

Brand Name	Generic Name	Dosage Form
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
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

Brand Name	Generic Name	Dosage Form
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.

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 Obesity as 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).

Vyvanse

Vyvanse is 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.
- Vyvanse is 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 Vyvanse for the treatment of obesity have not been established.

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), dexamethylphenidate (Focalin), or dexamethylphenidate 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), dexamethylphenidate (Focalin), or dexamethylphenidate 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 Azstarys, Daytrana, Desoxyn, Dyanavel XR, Jornay PM, Mydayis, Qelbree, QuilliChew ER, Quillivant XR, Strattera, Vyvanse, and Xelstryl 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

Drug	Quantity / 25 days	Quantity / 75 days
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

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

Drug	Quantity / 25 days	Quantity / 75 days
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

References

1. Adderall [package insert]. Parsippany, NJ: Teva Pharmaceuticals; May 2024.
2. Adderall XR [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
3. Adzenys XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; October 2023.
4. Aptensio XR [package insert]. Wilson, NC: Rhodes Pharmaceuticals; October 2023.
5. Azstarys [package insert]. Boston, MA: Corium, LLC; October 2023.
6. Concerta [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2023.
7. Cotelma XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; June 2021.
8. Daytrana [package insert]. Miami, FL: Noven Therapeutics, LLC; April 2024.
9. Desoxyn [package insert]. Tampa, FL: Ajenat Pharmaceuticals, LLC; September 2024.
10. Dexedrine Spansule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 2023.
11. Dextroamphetamine sulfate [package insert]. Parsippany, NJ: Teva Pharmaceuticals; September 2023.
12. Dyanavel XR [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc; October 2023.
13. Evekeo [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
14. Evekeo ODT [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
15. Focalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
16. Focalin XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
17. Jornay PM [package insert]. Morrisville, NC: Ironshore Pharmaceuticals Inc.; October 2023.
18. Metadate CD [package insert]. Denver, CO: Aytu BioPharma; October 2023.
19. Methylin Solution [package insert]. Florham Park, NJ: Shionogi Inc.; November 2023.
20. Methylphenidate Hydrochloride Chewable Tablets [package insert]. Lawrenceville, GA: XLCare Pharmaceuticals, Inc.; September 2023.
21. Methylphenidate Hydrochloride Extended Release Tablet [package insert]. Newtown, PA: KVK-Tech, Inc.; February 2024.
22. Methylphenidate Hydrochloride (LA) [package insert]. Raleigh, NC: Mayne Pharma; November 2022.
23. Methylphenidate Osmotic Extended Release [package insert]. Alpharetta, GA: Trigen Laboratories, LLC; October 2023.
24. Mydayis [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
25. ProCentra [package insert]. Newport, KY: Independence Pharmaceuticals, LLC; July 2023.
26. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; April 2022.
27. QuilliChew ER [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, Inc.; October 2023.
28. Quillivant XR [package insert]. Monmouth Junction, NJ: NextWave Pharmaceuticals, Inc.; October 2023.
29. Relexxii [package insert]. Alpharetta, GA: Vertical Pharmaceuticals, LLC; May 2024.
30. Ritalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
31. Ritalin LA [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.

32. Strattera [package insert]. Indianapolis, IN: Lilly USA, LLC; January 2022.
33. Vyvanse [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
34. Xelstryl [package insert]. Miami, FL: Noven Pharmaceuticals, Inc.; October 2023.
35. Zenzedi [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
36. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 9, 2024.
37. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 9, 2024.
38. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/09/2024).
39. Pliszka S. Practice Parameter for the Assessment and Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry. 2007;46(7):894-921.
40. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. Fifth Edition Text Revision. Arlington, Virginia: American Psychiatric Association; 2022.
41. Wolraich ML, Hagan JF, Allan C, et al. AAP Subcommittee On Children And Adolescents With Attention-Deficit/Hyperactive Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528.
42. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
43. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881-1893.
44. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Cancer-Related Fatigue. V.2.2024. Available at: www.nccn.org. Accessed November 4, 2024.