

Initial Prior Authorization

Amphetamines

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

Dextroamphetamines

Brand Name	Generic Name	Dosage Form
Dexedrine	dextroamphetamine	all products
dextroamphetamine (all other brands)	dextroamphetamine	all products
ProCentra	dextroamphetamine	all products

Reference number(s)
14-A, 1261-A

Brand Name	Generic Name	Dosage Form
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

Indications

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) in adults and pediatric patients 6 years and older.

Adzenys XR-ODT, Dyanavel XR

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

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.

Evekeo ODT

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

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.

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.

Compendial Uses

Narcolepsy^{15-17,21}

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).

Binge Eating Disorder (BED)

Authorization may be granted when the requested drug is being prescribed for the treatment of moderate to severe binge eating disorder (BED) when the following criteria is met:

- The request is for Vyvanse.

Narcolepsy

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

- 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 has 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.

Binge Eating Disorder (BED)

Authorization may be granted when the requested drug is being prescribed for the treatment of moderate to severe binge eating disorder (BED) when ALL of the following criteria are met:

- The request is for Vyvanse
- The patient achieved or maintained improvement in symptoms of BED 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 the following criteria is met:

- The patient achieved or maintained improvement in daytime sleepiness with narcolepsy from baseline.

Duration of Approval (DOA):

- 14-A: DOA: 36 months
- 1261-A: 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. Desoxyn [package insert]. Tampa, FL: Ajenat Pharmaceuticals, LLC; September 2024.
5. Dexedrine Spansule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 2023.
6. Dextroamphetamine sulfate [package insert]. Parsippany, NJ: Teva Pharmaceuticals; September 2023.
7. Dyanavel XR [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
8. Evekeo [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
9. Evekeo ODT [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
10. Mydayis [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
11. ProCentra [package insert]. Newport, KY: Independence Pharmaceuticals, LLC; July 2023.
12. Vyvanse [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
13. Xelstrym [package insert]. Miami, FL: Noven Pharmaceuticals, Inc.; October 2023.
14. Zenzedi [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
15. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 9, 2024.
16. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 9, 2024.
17. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/09/2024).
18. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision. Arlington, Virginia: American Psychiatric Association; 2022.
19. 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.
20. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
21. 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.