Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for amphetamine products under the member's prescription drug benefit.

Description:

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.

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.

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

Dextroampetamine 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.

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[16-18,22]

Applicable Drug List:

Reference Formulary for specific drugs

Policy/Guideline:

Documentation for Initial Requests for all indications:
For non-preferred medication requests, the patient is unable to take three (3) formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

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 Arynta or 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 Arynta or 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.

Approval Duration and Quantity Restrictions:

Approval: Initial and Renewal - Approve 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

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. Arynta [package insert]. Woborn, MA: Azurity Pharmaceuticals, Inc.; June 2025.
5. Desoxyn [package insert]. Tampa, FL: Ajenat Pharmaceuticals, LLC; September 2024.
6. Dexedrine Spansule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 2023.
7. Dextroamphetamine sulfate [package insert]. Parsippany, NJ: Teva Pharmaceuticals; September 2023.
8. Dyanavel XR [package insert]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
9. Evekeo [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
10. Evekeo ODT [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
11. Mydayis [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
12. ProCentra [package insert]. Newport, KY: Independence Pharmaceuticals, LLC; July 2023.
13. Vyvanse [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
14. Xelstrym [package insert]. Miami, FL: Noven Pharmaceuticals, Inc.; October 2023.
15. Zenzedi [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
16. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed October 9, 2024.
17. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed October 9, 2024.
18. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/09/2024).
19. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Text Revision. Arlington, Virginia: American Psychiatric Association; 2022.
20. 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.

21. American Academy of Sleep Medicine. International Classification of Sleep Disorders, Third Edition, Text Revision. American Academy of Sleep Medicine, 2023.
22. 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.