



AMPHETAMINES

Adderall, Adderall XR, Mydayis (mixed salts of a single entity amphetamine)
Adzenys XR-ODT*, Adzenys ER, Dyanavel XR*, Evekeo, Evekeo ODT* (amphetamine)
Desoxyn* (methamphetamine)
Dexedrine, Procentra, Xelstrym, Zenzedi (dextroamphetamine)
Vyvanse (lisdexamfetamine)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Amphetamine is a CNS stimulant and DEA schedule II drug, which is FDA approved for attention deficit hyperactivity disorder (ADHD) and narcolepsy. The exact mechanism by which amphetamines exert their action is unknown; however, amphetamines are thought to block the reuptake of norepinephrine and dopamine by the presynaptic neuron. This causes an increase in the release of these monoamines into the extra-neuronal space and increases their levels in the brain (1-13).

Attention deficit disorder (ADD) is no longer a medical diagnosis; however, it is often used to refer to predominantly inattentive type ADHD and associated symptoms. The terms ADD and ADHD will be used throughout this policy (14).

For patients 22 years of age and older prior authorization and review is required for both diagnosis and quantity requested. For patients 21 years of age and younger review is required if the total daily dose exceeds the FDA recommended daily limit.

Regulatory Status

FDA-approved indications: The products addressed by this policy are approved for use in the treatment of attention deficit hyperactivity disorder (ADHD) and narcolepsy (1-13). Vyvanse is also indicated for moderate to severe binge eating disorder (6).

Limitations of Use:

Vyvanse is not indicated 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 treatment of obesity have not been established (6).

Vyvanse and other stimulants are not indicated for weight loss (1-13).

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Off-Label Uses:

Amphetamines can be used as adjunctive therapy in the treatment of resistant depression (14).

Amphetamines have a boxed warning for high abuse and addiction potential. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events.

Other safety issues associated with amphetamines include sudden death in patients who have heart defects. Strokes, myocardial infarction, seizures, visual disturbances, adverse psychiatric reactions, and hypertension have been reported (1-13).

Summary

Amphetamine is a CNS stimulant and DEA schedule II drug, which is FDA approved for attention deficit hyperactivity disorder (ADHD) and narcolepsy. Amphetamines have a boxed warning for high abuse and addiction potential. Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events (1-13).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of amphetamines while maintaining optimal therapeutic outcomes.

References

1. Adderall [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA; October 2023.
2. Adderall XR [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
3. Desoxyn [package insert]. Tampa, FL: Ajenat Pharmaceuticals, LLC; September 2024.
4. Dexedrine Spansule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 2023.
5. Zenzedi [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
6. Vyvanse [package insert]. Lexington, MA: Shire US Inc.; October 2023.
7. Evekeo [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.

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8. Evekeo ODT [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
9. Dyanavel XR [package insert]. Monmouth Junction, NJ: Tris Pharma Inc.; October 2023.
10. Adzenys XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics Inc.; October 2023.
11. Mydayis [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
12. Adzenys ER solution [package insert]. Grand Prairie, TX: Neos Therapeutics Inc.; January 2022.
13. Xelstryl [package insert]. Noven Therapeutics, LLC; October 2023.
14. Lange, Klaus W et al. "The history of attention deficit hyperactivity disorder." Attention Deficit and Hyperactivity Disorders (Nov 2010) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3000907/>
15. Stoltz, Gabriele. MD; PhD, Woggon, Brigitte. MD., & Angst, Jules. (1999). Psychostimulants in the therapy of treatment-resistant depression Review of the literature and findings from a retrospective study in 65 depressed patients. 1. 165-74.