Clinical Policy Title:	methamphetamine
Policy Number:	RxA.96
Drug(s) Applied:	Desoxyn®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Methamphetamine (Desoxyn®) is a member of the amphetamine group of sympathomimetic amines. Desoxyn® is indicated:

- For the treatment of attention deficit hyperactivity disorder (ADHD) as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children over 6 years of age with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional liability, and impulsivity.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
methamphetamine (Desoxyn®)	ADHD	Initially, 5 mg PO once or twice a day; daily dosage may be raised in increments of 5 mg at weekly intervals until an optimal clinical response is achieved (usual effective dose: 20-25 mg daily given in two divided doses)	25 mg/day

Dosage Forms

- Tablets: 5 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Diagnosis of ADHD;
2. Age ≥ 6 years;
3. Dose does not exceed 25 mg/day.

Approval Duration

Commercial: 12 months
Medicaid: 12 months

II. **Continued Therapy Approval**

A. Attention Deficit Hyperactivity Disorder (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Dose does not exceed 25 mg/day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ADHD: attention deficit hyperactivity disorder
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of drug abuse, agitated state, advanced arteriosclerosis, symptomatic cardiovascular disease, concomitant use of MAOIs, or use within 14 days of stopping MAOIs, glaucoma, moderate to severe hypertension, hyperthyroidism, hypersensitivity to amphetamine or any component of the product, hypersensitivity or idiosyncrasy to sympathomimetic amines.

- Boxed Warning(s):
  - Methamphetamine has a high potential for abuse. Misuse of methamphetamine may cause sudden death and serious cardiovascular adverse events.

APPENDIX D: General Information

- FDA requested removal of weight management indication: Under Docket FDA-1979-N-0328, FDA concluded that because of the evidence of continuing misuse and abuse of amphetamines, the severe risk of dependence and harmful effects that these drug products present, and the availability of alternative drugs with less risk, the continued marketing of the drugs for use as an anorectic agent create an unfavorable benefit-to-risk ratio when compared to the limited benefit expected. FDA proposed to remove the indication for the management of exogenous obesity from the labeling of drug products containing an amphetamine.
- Tolerance to the anorectic effect of methamphetamine usually develops within a few weeks. When this occurs, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

References

1. Desoxyn Prescribing Information. Lebanon, NJ: Recordati Rare Diseases, Inc.; March 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/005378s035lbl.pdf. Accessed February 11, 2021.
2. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and

obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation. 2014; 129(suppl 2): S102–S138. Accessed February 11, 2021.
3. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100(2): 42362. Accessed February 11, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1) Clinical policy title was updated as "methamphetamine". 2) Line of business policies applies to All lines of business. 3) Background information was added as "characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional liability, and impulsivity". 4) Initial approval criteria I.A. " weight management" info removed and updated. 5) Continuation therapy criteria II.A.1. rephrased to "Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy." 6) References were reviewed and updated.	02/11/2021	03/09/2021