Clinical Policy: Methamphetamine (Desoxyn)

Reference Number: CP.CPA.333
Effective Date: 06.01.18
Last Review Date: 05.20
Line of Business: Commercial

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

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.

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® that Desoxyn is **medically necessary** when the following criteria are met:

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 per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Dose does not exceed 25 mg per day.

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial.

IV. Appendices/General Information

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, hypersensitive to amphetamine or any component of the product or known hypersensitivity or idiosyncrasy to sympathomimetic amines
- Boxed warning(s): none reported

Appendix D: General Information
- 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.

Appendix E: Desoxyn for Weight Management
- 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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
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 optimum clinical response is achieved (usual effective dose: 20-25 mg daily given in two divided doses)	25 mg/day

VI. Product Availability

Tablets: 5 mg

VII. 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 5, 2020.
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.
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): 42-362.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: split from CP.CPA.197 Weight Loss; removed requirement for documentation of baseline weight; removed required trial of Xenical for consistency with management of other stimulants; for re-auth: removed "continuation in a formalized weight management program" as this is difficult to verify/enforce; added that BMI must be ≥ 25 kg/m^2; limited total treatment duration to 12 weeks, consistent with criteria for other amphetamine stimulants used for anti-obesity and per FDA labeling for short-term use only; ADHD: added age requirement per PI; references reviewed and updated.	02.12.18	05.18
2Q 2019 annual review: no significant changes; added contraindications and boxed warnings; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: removed indication and criteria for weight management as per FDA statement referenced in Appendix E; references reviewed and updated.	02.05.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.