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ADHD Agents (Adult) Prior Authorization Criteria

Brand	Generic	Dosage Form
Adderall [®]	amphetamine/dextroamphetamine	oral tablet ^a
Adderall XR [®]	amphetamine/dextroamphetamine	extended-release oral capsule
DextroStat [®]	dextroamphetamine	oral tablet ^a
Dexedrine [®]	dextroamphetamine	extended-release capsule ^a
Liquadd [™]	dextroamphetamine	oral solution
Vyvanse [®]	lisdexamfetamine	oral capsule
Desoxyn [®]	methamphetamine	oral tablet
Ritalin [®]	methylphenidate	oral tablet ^a
Ritalin LA [®]	methylphenidate	extended-release tablet
Ritalin SR [®]	methylphenidate	extended-release tablet ^a
Methylin [®] ^b	methylphenidate	chewable tablet, oral solution
Metadate [®] CD	methylphenidate	extended-release capsule
Metadate [®] ER	methylphenidate	extended-release capsule ^a
Concerta [®]	methylphenidate	extended-release tablet
Daytrana [™]	methylphenidate	transdermal system
Focalin [®]	dexamethylphenidate	oral tablet ^a
Focalin [®] XR	dexamethylphenidate	extended-release capsule
Strattera [®]	atomoxetine	oral capsule

^a generic available

^b Methylin[®] chewable tablets and Methylin[®] oral solution are considered brand agents and will edit as a target drug. Methylin[®] oral tablet and Methylin[®] ER edit as generic agents and are accepted as generic prerequisites.

FDA APPROVED INDICATIONS¹⁻¹⁸

Agent	FDA Labeled Indication (age restrictions-years)		
	Narcolepsy	ADHD	Other
amphetamine/dextroamphetamine (Adderall, Adderall XR)	√ (Adderall)	√ (Adderall ≥ 3) (Adderall XR ≥ 6)	
dexamethylphenidate (Focalin, Focalin XR)		√ (≥ 6)	
Dextroamphetamine (Dexedrine, DextroStat, Liquadd)	√ (≥ 6)	√ (≥ 3)	
Lisdexamfetamine (Vyvanse)		√ (≥ 6)	
Methamphetamine (Desoxyn)	√ (≥ 6)	√ (≥ 6)	√ exogenous obesity (≥ 12)
Methylphenidate (Ritalin, Ritalin LA, Metadate ER, Metadate CD, Methylin, Concerta, Daytrana)	√ (Ritalin, Ritalin SR, Methylin)	√ (≥ 6)	
Atomoxetine (Strattera)		√	

ADHD=attention deficit hyperactivity disorder

RATIONALE FOR PRIOR AUTHORIZATION

The intent of the prior authorization (PA) criteria for the attention deficit hyperactivity disorder (ADHD) agents is to appropriately select patients according to product labeling and/or clinical guidelines and/or clinical studies and to direct use to more cost-effective generic agents as appropriate. The age edit of eighteen years or older is included in the PA criteria because clinical trials define child and adolescent ages as through 17 years of age and adults as 18 years of age and above. These criteria use the term ADHD to encompass both ADHD and attention deficit disorder (ADD).

Treatment guidelines authored by the American Academy of Child and Adolescent Psychiatry for assessment and treatment of children and adolescents with ADHD, the National Institute for Health and Clinical Excellence (NICE, 2006) and the Institute for Clinical Systems Improvement (ICSI, 2007) recommend use of any agent approved for the treatment of ADHD as initial pharmacologic treatment.¹⁹⁻²¹ This includes dextroamphetamine, methylphenidate, mixed salts amphetamine, and atomoxetine. The NICE Technology Appraisal evaluating ADHD agents for this recommendation considered the evidence on clinical effectiveness and concluded that methylphenidate, atomoxetine and dexamfetamine are effective in controlling the symptoms of ADHD relative to no treatment. Studies that included direct comparisons of different drugs and formulations, in general, reported few differences in measures of effectiveness. Methodologic flaws were found in studies that reported statistically significant differences in effectiveness.²⁰ Because of large variations across the trials in measures of efficacy, the variable reporting of adverse events, and the lack of long-term studies, the Nice Appraisal Committee was not able to differentiate between the drugs on clinical evidence.²⁰

An Oregon Health & Science University drug class review on pharmacologic treatments for ADHD developed by the Evidence-based Practice Center compared the benefits and harms of different pharmacologic treatments for ADHD.²² There were no conclusions made concerning the effectiveness of the different pharmacotherapies for ADHD. However, the reviewers state that evidence for comparative efficacy and adverse events for these agents is limited by small sample sizes, very short durations, and lack of studies measuring functional or long-term outcomes. The methods used to measure symptom control vary significantly among studies. Existing head-to-head trials were not considered of good quality by the reviewers and the small numbers of patients in these trials limits the ability to show a difference between drugs, if one exists.²²

The decision regarding the initial pharmacologic treatment of ADHD is based on several factors including the different adverse effects of the agents, issues regarding compliance, potential drug diversion and/or misuse, the presence of comorbid conditions, and the preference of the patient.¹⁹ For instance, treatment with an extended-release agent may be preferred over multiple daily dosing or if drug diversion is a consideration. Atomoxetine may be considered as a first choice agent for individuals with an active substance abuse problem, comorbid anxiety, or tics.¹⁸ Atomoxetine may be preferred if the patient experiences severe side effects or contraindications to psychostimulants.²¹ Contraindications may include, but are not limited to glaucoma, advanced arteriosclerosis, symptomatic cardiovascular disease, hypertension, hyperthyroidism, anxiety, agitation, Tourettes, motor tics, or history of drug abuse.¹⁻¹⁷

Extended-release formulations are available for many of the agents decreasing some of the difficulties associated with multiple daily dosing such as compliance, the social stigma and inconvenience of taking medications in a school setting, and the potential of drug diversion. Generic versions of amphetamines and methylphenidate are marketed in immediate-release and extended-release formulations. Atomoxetine is not yet available as a generic but may be approved for use as a first-line agent for the treatment of ADHD through the manual prior authorization (PA) process.

Many of the psychostimulant agents for ADHD have FDA-approved labeling for the treatment of narcolepsy. The European Federation of Neurological Society in a 2006 guideline for the treatment of narcolepsy recommends modafinil as the first-line treatment for excessive daytime sleepiness

and methylphenidate as a second-line choice.²³ The American Academy of Sleep Medicine in a practice parameter for narcolepsy published in 2000, suggests amphetamine, methamphetamine, dextroamphetamine, methylphenidate and modafinil as effective agents.²⁴ With the exception of modafinil, which is not included as a target drug in this program, agents are available as generics and when prescribed for the treatment of narcolepsy will be subject to the same step edit and PA requirements as for an ADHD diagnosis. Because the Sleep Medicine practice parameter recommends the ADHD agents, in general, for treatment of narcolepsy, the PA criteria will not differentiate the psychostimulants by diagnosis for the treatment of ADHD and narcolepsy. There are no generic agents in this program approved for the treatment of obesity. Desoxyn may be approved through the manual PA process when prescribed for this indication.

Compendia, including the United States Pharmacopeia Drug Information for the Health Care Professional (USPDI), the American Hospital Formulary Service (AHFS) Drug Information and Micromedex DrugDex, do not recommend any off-label uses for these agents. The PA criteria will not approve the psychostimulants or Strattera for off-label use unless the prescriber is able to provide evidence or documentation in support of use for the intended diagnosis.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Brand ADHD Agents

Initial and Renewal Evaluation

1. Is the patient eighteen years of age or older?
If yes, continue to 2. If no, refer to ADHD agents (Pediatric) Step Therapy Criteria.
2. Has the patient been diagnosed with adult ADHD or narcolepsy?
If yes, continue to 3. If no, continue to 6.
3. Has the patient tried and failed at least one of generic psychostimulant agent (amphetamine, dextroamphetamine, mixed amphetamine salts, methylphenidate, dexamethylphenidate) approved for treating ADHD or narcolepsy?
If yes, approve indefinitely. If no, continue to 4.
4. Does the patient have an allergy, contraindication or intolerance to generic agents?
If yes, approve indefinitely. If no, continue to 5.
5. Has the patient been prescribed Strattera due to comorbid conditions, concerns about controlled substance use, or after a trial and failure of a psychostimulant?
If yes, approve indefinitely. If no, continue to 6.
6. Is the brand requested Desoxyn prescribed for the treatment of obesity?
If yes, approve for 12 months. If no, continue to 7.
7. Has the physician submitted evidence in support of the use of the prescribed ADHD agent for the intended diagnosis?
If yes, pharmacist must review and may approve for 12 months. If no, deny.

SUMMARY

The criteria for the ADHD agents applies to patients who are 18 years of age or older and encourages the use of cost-effective generics before brand agents. Generics are available for many of the immediate- and extended-release psychostimulant ADHD agents. The PA process allows approval of brand agents through the manual PA process when patients are unable to take a generic due to allergy, contraindication, intolerance, or if use of a controlled substance is a concern and allows off-label use when the prescriber submits evidence in support of use for the intended diagnosis.

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Document History

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