

PRIOR AUTHORIZATION POLICY

POLICY:

Attention Deficit Hyperactivity Disorder (ADHD) Stimulants

- Adderall® (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate, amphetamine aspartate immediate-release tablets – Teva, generics)
- Adderall XR® (mixed amphetamine salts [dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate, amphetamine aspartate] extended-release capsules – Shire US, generics)
- Adzenys XR-ODT™ (amphetamine extended-release orally disintegrating tablets – Neos Therapeutics)
- Aptensio XR™ (methylphenidate extended-release capsules - Rhodes)
- Concerta® (methylphenidate extended-release tablets – Janssen, generics)
- Daytrana® (methylphenidate transdermal system – Noven Pharmaceuticals)
- Desoxyn® (methamphetamine tablets – Recordati, generics)
- dextroamphetamine sulfate tablets – generics
- Dexedrine® Spansules® (dextroamphetamine sustained-release capsules – Amedra Pharmaceuticals, generics)
- Dyanavel™ XR (amphetamine extended-release oral suspension – Tris)
- Evekeo™ (amphetamine sulfate tablets – Arbor Pharmaceuticals)
- Focalin® (dexmethylphenidate immediate-release tablets – Novartis, generics)
- Focalin® XR (dexmethylphenidate extended-release capsules – Novartis, generics)
- Metadate® CD (methylphenidate extended-release capsules – UCB, generics)
- Metadate® ER (methylphenidate sustained-release tablets – UCB, generics)
- Methylin® (methylphenidate tablets, chewable tablets, and oral solution – Shionogi, generics [tablets and oral solution only])
- methylphenidate extended-release capsules (generics to discontinued Methylin™ ER)
- Procentra® (dextroamphetamine sulfate liquid – FSC Laboratories, generics)
- QuilliChew ER™ (methylphenidate extended-release chewable tablets – Pfizer)
- Quillivant™ XR (methylphenidate extended-release oral suspension – Pfizer)
- Ritalin® (methylphenidate immediate-release tablets – Novartis, generics)
- Ritalin® LA (methylphenidate extended-release capsules – Novartis, generics)
- Ritalin SR® (methylphenidate sustained-release tablets – Novartis, generics)
- Vyvanse® (lisdexamfetamine dimesylate capsules – Shire US)
- Zenzedi™ (dextroamphetamine tablets – Arbor Pharmaceuticals)

TAC APPROVAL DATE:

03/02/2016; selected revision 03/30/2016

LAY CRITERIA EFFECTIVE DATE: Previously in Effect

OVERVIEW

All of the central nervous system (CNS) stimulants are indicated for the treatment of attention deficit /hyperactivity disorder (ADD/ADHD).¹⁻²⁴ Dextroamphetamine sulfate tablets, Zenzedi, and Adderall (generics) are indicated in patients ≥ 3 years of age; the other products are indicated in patients ≥ 6 years of age. Adderall XR (generics), Adzenys XR-ODT, Vyvanse, Concerta (generics), and several

methylphenidate products are indicated for use in adults with ADHD. Several products are also indicated for the treatment of narcolepsy. Evekeo and methamphetamine tablets are also indicated as adjunctive therapy for the short-term (i.e., a few weeks) treatment of exogenous obesity.^{4,20} The limited usefulness of amphetamines should be weighed against possible risks inherent in use of the drugs. Vyvanse is the only stimulant medication indicated for the treatment of binge eating disorder.⁵ Approval for this indication was based on two 12-week randomized, double-blind, multi-center, parallel-group, placebo-controlled, dose-optimization studies in adults aged 18 to 55 years (n = 374 and n = 350) with moderate to severe BED. Patients from both studies on Vyvanse had a statistically significantly greater reduction from baseline in mean number of binge days/week at Week 12.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of ADHD agents. All approvals are provided for 3 years in duration.

Automation: An age edit targeting patients < 4 or > 18 years of age is recommended. Therefore, patients between the ages of 4 and 18 years will be approved at the point-of-service. For patients < 4 or > 18 years of age, coverage will be determined by prior authorization criteria.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of ADHD stimulants is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Attention Deficit/Hyperactivity Disorder (ADD/ADHD).** Approve for 3 years if the patient is ≥ 4 years of age.

All of the agents are indicated for the treatment of ADHD.¹⁻²⁴ Dextroamphetamine sulfate tablets, Evekeo, Zenzedi, and Adderall (generics) are indicated in patients ≥ 3 years of age; the other products are indicated in patients ≥ 6 years of age. However, the 2011 American Academy of Pediatrics (AAP) clinical practice guidelines for the diagnosis, evaluation, and treatment of ADHD in children and adolescents state that for preschool-aged children (4 to 5 years of age), parent- and/or teacher-administered behavior therapy should be prescribed as first-line treatment; methylphenidate may be prescribed if behavior interventions do not provide significant improvement and disturbance of function continues.²⁵⁻²⁶ The guidelines also note that dextroamphetamine is the only agent approved by the FDA for use in children < 6 years of age; however, this approval was based on less stringent criteria in force when the medication was approved rather than on empirical evidence of its safety and efficacy in this age group.

2. **Binge Eating Disorder.** Approve only Vyvanse for 3 years if the patient meets BOTH of the following criteria (A and B):
 - A) The patient is ≥ 18 years old; AND
 - B) The patient has tried one of the following medications (i.e., SSRI [citalopram, escitalopram, fluoxetine, paroxetine, sertraline], imipramine, topiramate, zonisamide) for binge eating disorder.

The American Psychiatric Association (APA) guideline on the treatment of patients with eating disorders (2006 with a Guideline Watch in 2012) suggests treatment with antidepressant medications, particularly SSRI antidepressants, is associated with at least a short-term reduction in binge eating behavior but, in most cases, not with substantial weight loss (recommended with substantial clinical

confidence); topiramate is effective for binge reduction and weight loss (recommended with moderate clinical confidence); and zonisamide may produce similar effects regarding weight loss (may be recommended on the basis of individual circumstances).⁵³⁻⁵⁴ The 2012 Guideline Watch references a 2011 literature review by a multinational task force on eating disorders which concluded that Grade A evidence supports the use of imipramine (with moderate risk-benefit ratio), sertraline and citalopram/escitalopram (all with good risk-benefit ratios), and topiramate (with moderate risk-benefit ratio), and Grade D evidence for fluvoxamine and fluoxetine (i.e., inconsistent results).

3. Narcolepsy. Approve for 3 years.

Dextroamphetamine sulfate (Dexedrine, Dexedrine Spansule, generics, Zenzedi), mixed amphetamine salts (Adderall, generics), amphetamine sulfate (Evekeo) and several methylphenidate products (e.g., Ritalin, Methylin, Ritalin-SR, Metadate ER, generics) are indicated for the treatment of narcolepsy.^{1-18,47,51} In addition, the practice parameters for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007, state that amphetamine, methamphetamine, dextroamphetamine, and methylphenidate are effective for treatment of daytime sleepiness due to narcolepsy.²⁷

Other Uses with Supportive Evidence

4. Adjunctive/Augmentation Treatment for Depression in Adults. Approve for 3 years if the patient is concurrently receiving other medication therapy for depression (e.g., selective serotonin reuptake inhibitors [SSRIs]).

The 2010 American Psychiatric Association (APA) practice guidelines for the treatment of patients with major depressive disorder (MDD) state that many clinicians find augmentation of antidepressants with low doses of stimulants such as methylphenidate or dextroamphetamine may help ameliorate otherwise suboptimally responsive depression, although not all clinical trials have shown benefits from this strategy.²⁸ There are no clear guidelines regarding the length of time stimulants should be coadministered.

5. Cancer-Related Fatigue. Approve for 3 years.

The National Comprehensive Cancer Network (NCCN) guidelines on cancer-related fatigue (version 1.2016) state to consider use of psychostimulants (i.e., methylphenidate) after other causes of fatigue have been ruled out and/or other management strategies have been attempted.²⁹

6. Fatigue associated with Human Immunodeficiency Virus (HIV) Infection. Approve for 3 years.

There are published placebo-controlled trials demonstrating the effectiveness of methylphenidate and dextroamphetamine in treating fatigue in patients with HIV.³⁰⁻³² In one 6-week, randomized, double-blind, placebo-controlled trial in ambulatory patients with HIV and persistent and severe fatigue (n = 144), a total of 41% of patients receiving methylphenidate (at a maximum dose of 60 mg/day) demonstrated clinically significant improvement vs. 15% of patients receiving placebo.³⁰ In one 2-week, randomized, double-blind, placebo-controlled trial in men with HIV and depression and fatigue (n = 23), 73% of patients receiving dextroamphetamine reported significant improvement in mood and energy vs. 25% of patients receiving placebo.³¹

7. Fatigue or Sleepiness associated with Chronic Use of Narcotic Analgesics. Approve for 3 years.

Several review articles on opioid-induced sedation³³⁻³⁵ generally state that a paucity of data exist for the treatment of this condition. However, if non-pharmacologic options fail, some agents that may be useful, in addition to modafinil, include methylphenidate and dextroamphetamine. The 2008 American Pain Society (APS) guidelines on analgesic use in treatment of acute pain and cancer pain indicate that sedation during chronic narcotic analgesic treatment may be partially counteracted by adding a stimulant such as caffeine, dextroamphetamine, methylphenidate, or modafinil.³⁶ The NCCN guidelines on adult cancer pain (version 1.2016) state that sedation may hinder the achievement of dose titration of opioids to levels that provide adequate analgesia.³⁷ If opioid-induced sedation develops and persists for greater than 1 week, it may be managed by administration of a psychostimulant, such as methylphenidate, dextroamphetamine, or modafinil, or by adding caffeine.

8. **Idiopathic Hypersomnolence.** Approve for 3 years if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center).

Idiopathic hypersomnia, a condition similar to narcolepsy, is characterized by constant or recurrent daytime sleepiness with no other cause of sleepiness, prolonged nocturnal sleep, difficulty awakening with sleep drunkenness, and long unrefreshing naps with no history of cataplexy.³⁸⁻⁴¹ The practice parameters for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007, state that amphetamine, methamphetamine, dextroamphetamine, methylphenidate and modafinil may be effective for the treatment of daytime sleepiness due to idiopathic hypersomnia.²⁷ As there may be underlying causes/behaviors associated with excessive daytime sleepiness (EDS), a sleep specialist physician has the training to correctly recognize and diagnose this condition.

9. **Pervasive Developmental Disorders (e.g., autism, autistic disorder, Asperger's disorder).** Approve for 3 years in patients with symptoms of ADHD (e.g., inattention, hyperactivity).

Patients with pervasive developmental disorders who have symptoms of ADHD respond to ADHD stimulants at a reduced rate compared to typically developing peers, and often with undesirable side effects.⁴²⁻⁴⁴ However, there is evidence to support use of these agents in this patient population.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

ADHD stimulants have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Fatigue associated with Multiple Sclerosis (MS).** There are no published studies supporting this use. In addition, neither recent review articles nor the 2007 practice parameters for the treatment of narcolepsy and other hypersomnias of central origin mention stimulants (only modafinil). Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007, state that modafinil may be effective for the treatment of daytime sleepiness due to MS.²⁷ Agents that have been studied for the treatment of fatigue due to MS include amantadine, modafinil, pemoline, aminopyridines, antidepressants, and aspirin.⁵¹
2. **Long-term Combination Therapy (i.e., > 2 months) with CNS Stimulants and Strattera.** Currently, data do not support using Strattera and CNS stimulant medications concomitantly.⁵² Short-term drug therapy (≤ 2 months) with both Strattera and CNS stimulant medications are allowed for transitioning the patient to only one drug. Intuniv and clonidine extended-release tablets (Kapvay,

generics) are indicated for use as monotherapy, or as adjunctive therapy to CNS stimulant medications; therefore, long-term combination therapy with either agent and CNS stimulants is appropriate.⁴⁵⁻⁴⁶

3. **Neuroenhancement.** The use of prescription medication to augment cognitive or affective function in otherwise healthy individuals (also known as neuroenhancement) is increasing in adult and pediatric populations.⁴⁷ A 2013 Ethics, Law, and Humanities Committee position paper, endorsed by the American Academy of Neurology (AAN) indicates that based on currently available data and the balance of ethics issues, neuroenhancement in legally and developmentally nonautonomous children and adolescents without a diagnosis of a neurologic disorder is not justifiable. In nearly autonomous adolescents, the fiduciary obligation of the physician may be weaker, but the prescription of neuroenhancements is inadvisable due to numerous social, developmental, and professional integrity issues.
4. **Weight Loss.** Of the ADHD stimulants, only amphetamine and methamphetamine are indicated for exogenous obesity, as a short-term (i.e., a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to alternative therapy (e.g., repeated diets, group programs, and other drugs).^{4,51} However, guidelines on the management of obesity do not address or recommend use of amphetamine or methamphetamine (or any other ADHD stimulants).⁴⁸⁻⁵⁰
5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date	Lay Criteria Effective Date
Integrated policy	New policy	05/15/2013	--
Selected revision	Automation was added to the policy to target patients between the ages of 4 and 18 years. As such, criteria for the conditions of ADD/ADHD were changed to remove the requirement for behavior interventions.	06/05/2013	--
Selected revision	Selected revision to add Zenedi.	06/26/2013	--
Annual revision	Included generics to Focalin XR and Procentra. Removed reference to the discontinued brand Methylin ER.	05/21/2014	Previously in Effect
Selected revision	Approval duration increased to 3 years from 1 year.	08/06/2014	08/26/2014
Annual revision	Addition of criterion for new FDA-approved indication for Vyvanse in binge eating disorder. Evekeo added to the policy.	02/25/2015	03/05/2015
Selected revision	Addition of Aptensio XR to the policy. No change to criteria.	05/27/2015	Previously in Effect
Annual revision	Addition of Dyanavel XR and QuilliChew ER to the policy. No change to criteria.	03/02/2016	03/03/2016
Selected revision	Addition of Adzenys XR-ODT to the policy. No change to criteria.	03/30/2016	Previously in Effect

* For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>; TAC – Therapeutic Assessment Committee; ADD/ADHD – Attention deficit/hyperactivity disorder; FDA - Food and Drug Administration.