PRIOR AUTHORIZATION POLICY

POLICY: Attention Deficit Hyperactivity Disorder Stimulant Medications Prior Authorization Policy

- 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)
- Adhansia XR™ (methylphenidate extended-release capsules – Adlon/Purdue)
- Adzenys ER™ (amphetamine extended-release oral suspension – Neos Therapeutics)
- 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)
- Cotempla XR-ODT™ (methylphenidate extended-release orally disintegrating tablets – Neos Therapeutics)
- Daytrana® (methylphenidate transdermal system – Noven Pharmaceuticals)
- Desoxyn® (methamphetamine tablets – Recordati, generics)
- dextroamphetamine sulfate tablets – generics
- Dexedrine® Spansules® (dextroamphetamine sustained-release capsules – Impax, generics)
- Dyanavel™ XR (amphetamine extended-release oral suspension – Tris)
- Evekeo™ (amphetamine sulfate tablets – Arbor Pharmaceuticals)
- Evekeo ODT™ (amphetamine sulfate orally disintegrating tablets – Arbor Pharmaceuticals)
- Focalin® (dexmethylphenidate immediate-release tablets – Novartis, generics)
- Focalin® XR (dexmethylphenidate extended-release capsules – Novartis, generics)
- Jornay PM™ (methylphenidate hydrochloride extended-release capsules – Ironshore)
- 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)
- methylphenidate extended-release capsules (generics to discontinued Methylin™ ER)
- methylphenidate 72 mg extended-release tablets (branded product – Trigen)
- Mydayis™ (mixed salts of a single-entity amphetamine product extended-release capsules – Shire)
- Procentra® (dextroamphetamine sulfate liquid – FSC Laboratories, generics)
- QuilliChew ER™ (methylphenidate extended-release chewable tablets – Pfizer)
- Quillivant™ XR (methylphenidate extended-release oral suspension – Pfizer)
- Relexxii® (methylphenidate extended-release tablets – Vertical [branded generic])
- 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 and chewable tablets – Shire)
- Zenzedi™ (dextroamphetamine tablets – Arbor Pharmaceuticals)

REVIEW DATE: 08/05/2020

OVERVIEW

The central nervous system (CNS) stimulant medications in this policy are indicated for:[1-24,45,46,50-54]

- **Attention deficit hyperactivity disorder (ADHD)**, treatment. All of the stimulant medications in this policy are indicated for the treatment of ADHD.
- **Binge eating disorder (BED)**, treatment. Vyvanse is the only stimulant medication indicated for the treatment of BED.
- **Narcolepsy**, treatment. Several methylphenidate and amphetamine-containing products are also indicated for the treatment of narcolepsy.
- **Exogenous obesity**, treatment. Evekeo is indicated as adjunctive therapy for the short-term (i.e., a few weeks) treatment of exogenous obesity.

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, except for Mydayis which is indicated in patients ≥ 13 years of age. Adderall XR (generics), Adzenys ER, Adzenys XR-ODT, Mydayis, Vyvanse, Concerta (generics), and several methylphenidate products are indicated for use in adults with ADHD. Jornay PM is the only stimulant taken in the evening.

Disease Overview

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.[31-34]

Guidelines

Eating disorders: 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 selective serotonin reuptake inhibitors (SSRIs), 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).[43,44] 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).

Narcolepsy and other hypersomnias: The practice parameters from the American Academy of Sleep Medicine 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] The parameters also state that amphetamine, methamphetamine, dextroamphetamine, methylphenidate and modafinil may be effective for the treatment of daytime sleepiness due to idiopathic hypersomnia. 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.

Major depressive disorder (MDD): The 2010 APA practice guidelines for the treatment of patients with 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. A 16-week randomized,

double-blind, placebo-controlled trial in patients with geriatric depression in older (mean age of 70 years) outpatients diagnosed with major depression (n = 143) found that combined treatment with citalopram and methylphenidate demonstrated an enhanced clinical response profile in mood and well-being, as well as a higher rate of remission, compared with either drug alone.[47]

Cancer-related fatigue: The National Comprehensive Cancer Network (NCCN) guidelines on cancer-related fatigue (version 2.2020 – May 4, 2020) 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] The NCCN guidelines on adult cancer pain (version 1.2020 – April 8, 2020) state that sedation may hinder the achievement of dose titration of opioids to levels that provide adequate analgesia.[30] If opioid-induced sedation develops and persists for greater than 2 to 3 days, it may be managed by administration of a psychostimulant, such as methylphenidate, dextroamphetamine, or modafinil, or by adding caffeine. A meta-analysis of treatments for fatigue associated with palliative care showed a superior effect for methylphenidate in cancer-related fatigue.[48] A review of methylphenidate for cancer-related fatigue found a small but significant improvement in fatigue over placebo (P = 0.005).[49]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ADHD stimulant medications in adults. Only patients ≥ 18 years of age will be required to meet the Prior Authorization criteria below. All approvals are provided for the duration noted below.

Automation: This policy includes an age edit targeting patients ≥ 18 years of age. Therefore, patients below the age of 18 years will be approved at the point-of-service. For patients ≥ 18 years of age, coverage will be determined by Prior Authorization criteria.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Attention Deficit Hyperactivity Disorder.** Approve for 1 year.

2. **Binge Eating Disorder.** Approve only Vyvanse for 1 year if the patient is ≥ 18 years of age.

3. **Narcolepsy.** Approve for 1 year.

Other Uses with Supportive Evidence

4. **Depression, Adjunctive/Augmentation Treatment in Adults.** Approve for 1 year if the patient is concurrently receiving other medication therapy for depression.
   Note: Examples of medications for the treatment of depression include selective serotonin reuptake inhibitors (SSRIs).

5. **Fatigue associated with Cancer and/or its Treatment.** Approve for 1 year.

6. **Idiopathic Hypersomnolence.** Approve for 1 year if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ADHD stimulant medications is not recommended in the following situations:

1. **Fatigue associated with Multiple Sclerosis.** 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.[41]

2. **Long-term Combination Therapy (i.e., > 2 months) with Strattera® (atomoxetine capsules) and Central Nervous System (CNS) Stimulants for the treatment of Attention Deficit/Hyperactivity Disorder (e.g., mixed amphetamine salts extended-release capsules [Adderall XR®, generics], methylphenidate extended-release tablets, methylphenidate immediate-release tablets).** Currently, data do not support using Strattera and CNS stimulant medications concomitantly.[42] 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.[35-36]

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.[37] A 2013 Ethics, Law, and Humanities Committee position paper, endorsed by the American Academy of Neurology (AAN) indicates that based on 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 CNS 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).[4,41] However, guidelines on the management of obesity do not address or recommend use of amphetamine or methamphetamine (or any other CNS stimulants).[38-40]

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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