PRIOR AUTHORIZATION POLICY

POLICY: Attention Deficit Hyperactivity Disorder Stimulant Medications Prior Authorization Policy

REVIEW DATE: 08/07/2024

OVERVIEW

The central nervous system (CNS) stimulant medications in this policy are indicated for the following uses:[1-24,43,44,48-54]

- **Attention deficit hyperactivity disorder** (ADHD**)**, treatment. All of the stimulant medications in this policy are indicated for the treatment of ADHD.
- **Binge eating disorder**, treatment. Vyvanse is the only stimulant medication indicated for the treatment of binge eating disorder.
- **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 (generic) 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.[1,2,6,19,43] Adderall XR (generic), Adzenys ER, Adzenys XR-ODT, Concerta (generic), Mydayis, Vyvanse, Xelstrym, and several methylphenidate products are indicated for use in adults with ADHD.[2,5,9,24,43,48,54] Jornay PM is the only stimulant taken in the evening.[49]

Other Uses with Supportive Evidence

Idiopathic hypersomnia: A condition similar to narcolepsy, idiopathic hypersomnia 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 of cataplexy.[29-32]

Guidelines

Narcolepsy and other hypersomnias: The practice parameters from the American Academy of Sleep Medicine for the treatment of central disorders of hypersomnolence (2021) state that dextroamphetamine and methylphenidate, in addition to other wakefulness-promoting agents, are effective for treatment of daytime sleepiness due to narcolepsy.[25] The parameters also state that methylphenidate, in addition to other agents, 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, a sleep specialist physician has the training to correctly recognize and diagnose this condition.

Major depressive disorder (MDD): The 2010 American Psychiatric Association 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.[26] There are no clear guidelines regarding the length of time stimulants should be co-administered. A 16-week randomized, double-blind, placebo-controlled trial in older outpatients with major depression (mean age of 70 years) [n = 143] found that combined treatment with citalopram and methylphenidate demonstrated an enhanced clinical response profile in mood and wellbeing, as well as a higher rate of remission, compared with either drug alone.[45]

Cancer-related fatigue: The National Comprehensive Cancer Network (NCCN) guidelines on cancer-related fatigue (version 2.2024 – October 30, 2023) state to consider use of psychostimulants (i.e., methylphenidate) in consideration of other modifiable causes.[27] The NCCN guidelines on adult cancer pain (version 2.2024 – March 11, 2024) state that sedation may hinder the achievement of dose titration of opioids to levels that provide adequate analgesia.[28] If opioid-induced sedation develops, it may be managed by administration of a psychostimulant, such as methylphenidate, dextroamphetamine, modafinil, armodafinil, 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.[46] A review of methylphenidate for cancer-related fatigue found a small but significant improvement in fatigue over placebo (P = 0.005).[47]

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: An age edit is in place such that a patient less than 18 years of age will be approved at the point of service. For a patient ≥ 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 one of the following criteria:

FDA-Approved Indications

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

2. **Binge Eating Disorder.** Approve only Vyvanse (brand or generic) 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 an Adult.** 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.

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 2021 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 2021, state that modafinil may be effective for the treatment of daytime sleepiness due to multiple sclerosis.[25] Agents that have been studied for the treatment of fatigue due to multiple sclerosis include amantadine, modafinil, and methylphenidate; these medications were not superior to placebo for this use.[41]

2. **Long-Term Combination Therapy (i.e., > 2 months) with atomoxetine capsules (Strattera®, generic) 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 atomoxetine and CNS stimulant medications is allowed for transitioning the patient to only one drug. Guanfacine extended-release tablets (Intuniv®, generic) and clonidine extended-release tablets (Kapvay®, generic) 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.[33,34]

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.[35] A 2013 Ethics, Law, and Humanities Committee position paper, endorsed by the American Academy of Neurology indicates that based on available data and the balance of ethics issues, neuroenhancement in legally and developmentally non-autonomous 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 sulfate tablets (e.g., Evekeo tablets) 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).[20] However, guidelines on the management of obesity do not address or recommend use of amphetamine (or any other CNS stimulants).[36-40]

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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