Drug Coverage Policy

Effective Date.....9/15/2024
Coverage Policy Number.....IP0584
Policy Title.....Attention Deficit Hyperactivity Disorder (ADHD) Stimulants for Individual and Family Plans

Attention Deficit Hyperactivity Disorder (ADHD) Stimulants for Individual and Family Plans

- **dextroamphetamine sulfate** immediate-release tablets
- **lisdexamfetamine dimesylate** capsules and chewable tablets
- **Metadate CD** (methylphenidate hydrochloride extended-release capsules)
- **methylphenidate** extended-release tablets 45mg, 63mg, and 72 mg
- **mixed salts of a single-entity amphetamine product** extended-release capsules (generic for Mydayis)
- **Mydayis**™ (mixed salts of a single-entity amphetamine product extended-release capsules)
- **Relexxii**® (methylphenidate extended-release tablets)
- **Vyvanse**® (lisdexamfetamine dimesylate capsules and chewable tablets)
- **Zenzedi**™ (dextroamphetamine tablets)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request

should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

Attention Deficit Hyperactivity Disorder (ADHD) stimulant products included in this policy are considered medically necessary when the individual meets BOTH of the following:

1. Documented diagnosis of **ONE** of the following:
    A. Attention Deficit Hyperactivity Disorder (ADD/ADHD)
    B. Binge-Eating Disorder in an Adult (18 years of age and older) [Vyvanse and lisdexamfetamine ONLY]
    C. Narcolepsy
    D. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following:
        i. Individual is 18 years of age or older
        ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs])
    E. Fatigue Associated with Cancer and/or its Treatment
    F. Idiopathic Hypersomnolence and meets the following:
        i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
2. Preferred Product Criteria is met, refer to below table(s)

Product	Criteria
dextroamphetamine sulfate immediate-release tablets 2.5mg, 7.5mg, 15mg, 20mg, 30mg	Documentation of **BOTH** of the following: 1. Failure or intolerance to generic dextroamphetamine 5mg or 10mg **OR** Zenzedi 5mg or 10mg 2. Failure, contraindication, or intolerance to **THREE** of the following: A. amphetamine (generic for Evekeo) **OR** dextroamphetamine/amphetamine (generic for Adderall) B. dexmethylphenidate (generic for Focalin) C. methamphetamine (generic for Desoxyn) D. methylphenidate chewable tablet **OR** methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin)
lisdexamfetamine dimesylate capsules	Documentation of failure, contraindication, or intolerance to **THREE** of the following [does NOT apply to a diagnosis of binge-eating disorder]: 1. dexmethylphenidate ER capsules (generic for Focalin XR) 2. dextroamphetamine/amphetamine ER capsules (generic for Adderall XR)

Product	Criteria
	3. dextroamphetamine ER capsules (generic for Dexedrine) 4. methylphenidate ER capsules (generics for Metadate CD or Ritalin LA) **OR** methylphenidate ER tablets (generic for Concerta)
lisdexamfetamine dimesylate chewable tablets	Documentation of failure, contraindication, or intolerance to **THREE** of the following [does NOT apply to a diagnosis of binge-eating disorder]: 1. dexmethylphenidate ER capsules (generic for Focalin XR) 2. dextroamphetamine/amphetamine ER capsules (generic for Adderall XR) 3. dextroamphetamine ER capsules (generic for Dexedrine) 4. methylphenidate ER capsules (generics for Metadate CD or Ritalin LA)
Metadate CD (methylphenidate hydrochloride extended-release capsules)	Documentation of **BOTH** of the following: 1. Trial of **methylphenidate extended-release capsule** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction 2. Failure, contraindication, or intolerance to **THREE** of the following: A. dexmethylphenidate ER capsules (generic for Focalin XR) B. methylphenidate ER tablets (generic for Concerta) C. methylphenidate LA capsules (generic for Ritalin LA) D. methylphenidate ER capsules (generic for Aptensio XR
methylphenidate extended-release 45mg, 63mg, 72 mg tablets	Documentation of failure, contraindication, or intolerance to **ALL** of the following: 1. dexmethylphenidate extended-release capsules (generic for Focalin XR) 2. methylphenidate extended-release tablets (generic for Concerta) 3. methylphenidate CD capsules (generic for Metadate CD) or methylphenidate LA capsules (generic for Ritalin LA) 4. methylphenidate extended-release capsules (generic for Aptensio XR)
mixed salts of a single-entity amphetamine product extended-release capsules (generic for Mydayis)	Documentation of **BOTH** of the following: 1. Age 13 years or older 2. Failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER capsules (generic for Focalin XR) B. dextroamphetamine/amphetamine ER capsules (generic for Adderall XR) C. dextroamphetamine ER capsules (generic for Dexedrine)

Product	Criteria
	D. methylphenidate ER capsules (generics for Metadate CD or Ritalin LA) **OR** methylphenidate ER tablets (generic for Concerta)
Mydayis (mixed salts of a single-entity amphetamine product extended-release capsules)	Documentation of **BOTH** of the following: 1. Age 13 years or older 2. Failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER capsules (generic for Focalin XR) B. dextroamphetamine/amphetamine ER capsules (generic for Adderall XR) C. dextroamphetamine ER capsules (generic for Dexedrine) D. methylphenidate ER capsules (generics for Metadate CD or Ritalin LA) **OR** methylphenidate ER tablets (generic for Concerta)
Relexxii (methylphenidate extended-release 18mg, 27mg, 36mg, 45mg, 54mg, 63mg, 72 mg tablets)	Documentation of failure, contraindication, or intolerance to **ALL** of the following: 1. dexmethylphenidate extended-release capsules (generic for Focalin XR) 2. methylphenidate extended-release tablets (generic for Concerta) 3. methylphenidate CD capsules (generic for Metadate CD) or methylphenidate LA capsules (generic for Ritalin LA) 4. methylphenidate extended-release capsules (generic for Aptensio XR)
Vyvanse capsules (lisdexamfetamine dimesylate)	Documentation of **BOTH** of the following: 1. Trial of **lisdexamfetamine capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction [may require prior authorization] 2. Failure, contraindication, or intolerance to **THREE** of the following [does NOT apply to a diagnosis of binge-eating disorder]: A. dexmethylphenidate ER capsules (generic for Focalin XR) B. dextroamphetamine/amphetamine ER capsules (generic for Adderall XR) C. dextroamphetamine ER capsules (generic for Dexedrine) D. methylphenidate ER capsules (generics for Metadate CD or Ritalin LA) **OR** methylphenidate ER tablets (generic for Concerta)
Vyvanse chewable tablets (lisdexamfetamine dimesylate)	Documentation of **BOTH** of the following: 1. Trial of **lisdexamfetamine chewable tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would

Product	Criteria
	result in a significant allergy or serious adverse reaction [may require prior authorization] 2. Failure, contraindication, or intolerance to **THREE** of the following [does NOT apply to a diagnosis of binge-eating disorder]: A. dexmethylphenidate ER capsules (generic for Focalin XR) B. dextroamphetamine/amphetamine ER capsules (generic for Adderall XR) C. dextroamphetamine ER capsules (generic for Dexedrine) D. methylphenidate ER capsules (generics for Metadate CD or Ritalin LA)
Zenzedi 2.5mg, 7.5mg, 15mg, 20mg, 30mg (dextroamphetamine tablets)	Documentation of **BOTH** of the following: 1. Failure or intolerance to dextroamphetamine 5mg or 10mg **OR** Zenzedi 5mg or 10mg 2. Failure, contraindication, or intolerance to **THREE** of the following: A. amphetamine (generic for Evekeo) **OR** dextroamphetamine/amphetamine (generic for Adderall) B. dexmethylphenidate (generic for Focalin) C. methamphetamine (generic for Desoxyn) D. methylphenidate chewable tablet **OR** methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Attention Deficit Hyperactivity Disorder (ADHD) stimulant products included in this policy are considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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.[41]

2. **Long-term Combination Therapy (i.e., > 2 months) with Strattera and Central Nervous System (CNS) Stimulants for the treatment of ADD/ADHD (for example, 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]

Background

OVERVIEW

The central nervous system (CNS) stimulant medications, including Vyvanse, are indicated for the following uses:[1-24,43,44,48-53]

- **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 (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.[1,2,6,19,43] Adderall XR (generics), Adzenys ER, Adzenys XR-ODT, Mydayis, Vyvanse, Concerta (generics), and several methylphenidate products are indicated for use in adults with ADHD.[2,5,9,24,43,48] 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 history of cataplexy.[29-32]

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).[39,40] 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.[25] 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, 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.[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 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 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 1.2021 – December 1, 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.[27] The NCCN guidelines on adult cancer pain (version 2.2021 – June 3, 2021) state that sedation may hinder the achievement of dose titration of opioids to levels that provide adequate analgesia.[28] 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, 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]

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Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	Added criteria for Metadate CD.	9/15/2024
Selected Revision	Added criteria for dextroamphetamine immediate-release tablets, methylphenidate ER tablets (45mg, 63mg, and 72mg), Relexxii, and Zenzedi.	4/1/2024