

Stimulant Drug Use Criteria for Adult Advanced Health Members ≥ 23 Years of Age

Created: 10/2015

Revised: 8/2018, 6/2019, 12/2021, 2/2022, 5/2022, 7/2023, 9/2023

Includes:

Focalin XR ©	<i>dexmethylphenidate</i>
Dexedrine ER©	<i>dextroamphetamine</i>
Vyvanse©	<i>Lisdexamfetamine</i>
Methylphenidate LA/CD capsules	

**Applies to all other stimulants not listed*

**Amphetamine/dextroamphetamine ER, amphetamine/dextroamphetamine IR, methylphenidate ER 10mg or 20 mg tablet, methylphenidate IR, dextroamphetamine IR, and dexmethylphenidate IR are available on formulary without a PA.*

GUIDELINE FOR USE:

Initial Request:

1. Is the patient being treated for a funded condition by Oregon Health Plan?
 - a. If yes, go to 2
 - b. If no, deny as Below the Line. The condition being treated is below the funded line for Oregon Health Plan and is therefore not a covered benefit.
2. Is the patient being treated for attention deficit disorder with or without hyperactivity or narcolepsy?
 - a. If ADHD, go to 3
 - b. If narcolepsy, go to 8
 - c. If no, deny as Criteria Not Met. Stimulant therapy will be provided as a covered benefit for FDA approved indications supported by the medication package insert. Off label use of medication is not a covered benefit on Oregon Health Plan.
3. Has the member trialed a formulary alternative for at least 30 days or is there clinical rationale to support contraindication/intolerance to formulary alternative? If request is for an IR version, trial of formulary IR alternative is required. If request if for an ER version, trial of formulary ER alternative is required.
 - a. If yes, go to 4
 - b. If no, deny as nonformulary. Formulary alternatives include amphetamine/dextroamphetamine ER, or amphetamine/dextroamphetamine IR,

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methylphenidate ER 10mg or 20mg tablets, methylphenidate IR tablets or dextroamphetamine IR tablets, or dexmethylphenidate IR tablets.

4. Is the request for Vyvanse (Lisdexamfetamine)?
 - a. If yes, go to 5
 - b. If no, go to 6

5. Has the member trialed at least 2 other least costly alternatives including dextroamphetamine ER (dexmethylphenidate ER, methylphenidate LA/CD capsules, methylphenidate ER tablet)? *Of note, Vyvanse is a prodrug of dextroamphetamine.
 - a. If yes, go to 6
 - b. If no, deny as not least costly alternative. Recommend trial of dextroamphetamine, dexmethylphenidate, methylphenidate LA/CD, or methylphenidate ER tab.

6. Is the medication prescribed by a mental health professional (PMHNP, psychiatrist, ADAPT mental health provider, etc)
 - a. If yes go to 11
 - b. If no, go to 7

7. Has the patient been evaluated and diagnosed with ADHD with or without hyperactivity and have co-morbid conditions that may contribute to ADHD symptoms been addressed (eg depression, anxiety, etc). Please provide documentation of assessment such as Adult ADHD Self-Report Scale (ASRS v1.1), Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder 7-item (GAD-7), clinical and historical interview. Demonstrated impairments should be present across multiple environmental domains (school, work, home, etc).
 - a. If yes, go to 8
 - b. If no, deny as Criteria Not Met. An evaluation and diagnosis of ADHD is required for coverage of stimulant therapy, including co-morbid conditions that may contribute to ADHD symptoms be addressed. Please submit documentation such as ASRS, PHQ-9, GAD-7, clinical and historical interview.

8. Does the patient have a history of substance abuse?
 - a. If yes, deny as Criteria Not Met. Schedule II stimulant medications have a high potential for abuse, misuse, and diversion. Use of stimulants are contraindicated in patients with a history of drug abuse. Consider therapy with a tricyclic antidepressant (desipramine or nortriptyline) or atomoxetine (Strattera). Bupropion is also an alternative if patients do not tolerate TCA therapy. Or provide clinical rationale to prescribing stimulant therapy to patient with history of substance abuse.
 - b. If no, go to 9

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9. Is the patient using any other medications that have a potential for causing sedation (*e.g. opioid pain medications, heavy alcohol use (SBRT), benzodiazepines, etc*). **Current UDS (within 90 days) is required.**
- If yes, deny as Criteria Not Met. Stimulant therapy is not indicated for treatment of sedation or fatigue due to side effects of concomitant therapies.
 - If no, continue to 10
10. *Has provider considered marijuana use as a contributing factor for sedation? Clinical rationale- please address reason for marijuana use and effect on ADLs.*
- If yes, go to 11
 - If no, please submit clinical rationale of using a stimulant with a substance that causes sedation.
11. Does the patient have blood pressure that is currently well controlled? (*Chart notes documenting blood pressure will be required*)
- If yes, go to 12
 - If no, deny as Criteria Not Met. Elevated blood pressure and heart rate are common side effects of stimulant therapy. Moderate to severe hypertension are contraindications to stimulant therapy. Consider therapy with clonidine for patients with ADHD and hypertension.
12. Does the patient have preexisting structural cardiac abnormalities or other serious cardiac problems?
- If yes, deny as Criteria Not Met. Use of stimulant therapy has been associated with serious cardiovascular events including sudden death in patients with preexisting structural cardiac abnormalities or other serious heart problems. Stimulants should be avoided in patients with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that can increase the risk of sudden death.
 - If no, go to 13
13. Does the patient have obstructive sleep apnea (OSA)?
- If no, go to 14
 - If yes, is OSA managed with continuous positive airway pressure therapy (CPAP) or alternative therapies such as oral appliances?
 - If yes, go to 14
 - If no, deny as Criteria not Met. Untreated OSA is associated with poor concentration, excessive daytime sleepiness, and fatigue, which may impair daily function or induce/exacerbate cognitive deficits. OSA should be adequately controlled prior to initiating treatment with stimulants.

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14. Does the patient have bipolar disorder, preexisting psychosis, anxiety disorder, agitated state, narrow angle or angle closure glaucoma, or hyperthyroidism? Or is there clinical rationale to prescribing a stimulant without treating comorbid conditions.
 - a. If yes, and written by a mental health professional, go to question 15
 - b. If yes, and written by a PCP or non-mental health professional, deny as Criteria Not Met. Stimulant therapy is not recommended in patients with bipolar disorder, preexisting psychosis, anxiety disorder, agitated state, glaucoma, or hyperthyroidism.
Note to reviewer: TCAs have been shown to be efficacious in adult ADHD. TCAs have also been shown in clinical trials to reduce anxiety in patients with ADHD and comorbid anxiety. Stimulants may exacerbate symptoms of behavior and thought disorder. Stimulants may induce mixed/manic episodes in patients with bipolar disorder. New onset psychosis or mania may also occur with stimulant use
SSRI/SNRI first, then add stimulant for anxiety (look at manufacturer labeling).
Uncontrolled anxiety will be allowed if prescribed by a mental health professional.
 - c. If no, go to 16

15. Does member have narrow angle or angle closure glaucoma, hyperthyroidism, preexisting psychosis, bipolar disorder, or schizophrenia?
 - a. If yes, send to MD review.
 - b. If no, go to 16

16. Is the patient taking a MAO inhibitor, or quit taking a MAO inhibitor within 14 days of starting stimulant therapy? (e.g. isocarboxazid, phenelzine, tranylcypromine, or selegeline)
 - a. If yes, deny as Criteria Not Met. Concomitant use of stimulants and MAO inhibitor therapy, or discontinuation within 14 days, is contraindicated due to increased risk of hypertensive crisis.
 - b. If no, go to 17

17. Is the prescribed dose supported by the FDA approved package insert dosing guideline for the prescribed product?
 - a. If yes, approve for the requested duration of therapy up to 12 months
 - b. If no, deny as Criteria Not Met. Doses above those supported by the FDA approved package insert are not a covered benefit on Oregon Health Plan.

Renewal Request:

1. Does the above criteria continue to be met and do chart notes support positive response to therapy?
 - a. If yes, approve for requested duration of therapy up to 12 months.
 - b. If no, deny as not meeting criteria.

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Rationale:

Stimulants used for the treatment of narcolepsy and attention deficit disorder with or without hyperactivity have a high propensity for abuse and diversion. Drug shortages of several stimulant medications have resulted in price increases for this class of drugs. Therefore, drug use criteria for stimulant therapy in adults is necessary to ensure appropriate patient selection, safety, and cost-effective management of ADHD and narcolepsy. Stimulant medications will not be approved for conditions not funded for coverage by Oregon Health Plan.

FDA Approved Indication and Dosing:

Drug	FDA Approved Indication	Maximum Daily Dose Adult/Pediatric	Duration of Action
amphetamine/dextroamphetamine (mixed amphetamine salts)	ADHD, narcolepsy	ADHD (≥6yo) 40mg/day Narcolepsy 60mg/day	5 to 8 hours (duration increases with increased dose)
Dexmethylphenidate	ADHD	20mg/day	4 to 5 hours
Dextroamphetamine	ADHD, narcolepsy	40mg/day	4 to 6 hours
Methylphenidate	ADHD, narcolepsy	60mg/day Peds: NTE 2mg/kg/day	3 to 5 hours

Accepted Symptom Checklists and Questionnaire Links:

- Adult ADHD Self-Report Scale (ASRS v1.1):
[http://www.mentalhealthprofessionalsinc.com/Forms/Adult_ADHD_Self-Report_Scale_\(ASRS-v1.1\).pdf](http://www.mentalhealthprofessionalsinc.com/Forms/Adult_ADHD_Self-Report_Scale_(ASRS-v1.1).pdf)
- Patient Health Questionnaire (PHQ-9):
<http://www.agencymeddirectors.wa.gov/Files/AssessmentTools/13-PHQ-9%20form.pdf>
- Generalized Anxiety Disorder 7-item (GAD-7):
<https://med.dartmouth-hitchcock.org/documents/GAD-7-anxiety-screen.pdf>

References:

1. Bukstein MD, Oscar. Attention deficit hyperactivity disorder in adults: Epidemiology, pathogenesis, clinical features, course, assessment, and diagnosis. UpToDate. Literature review current through June 2023. Accessed July 17, 2023.
2. Brent MD, David, Bukstein MD, Oscar, Solanto PhD, Mary. Management of attention deficit hyperactivity disorder in adults. UpToDate. Literature review current through June 2023. Accessed July 17, 2023.
3. Clinical Resource, Comparison of ADHD Medications. Pharmacist’s Letter/Prescriber’s Letter. September 2021. Accessed December 20, 2021.
4. Scammell MD, Thomas. Treatment of narcolepsy in adults. UpToDate. Literature review current through June 2023. Accessed July 17, 2023.

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5. Ritalin Prescribing Information. Novartis Pharmaceuticals Corporation. Revised 6/2021.
6. Micromedix Healthcare Series Database 2.0. DrugDex Evaluation: Methylphenidate.
7. Micromedix Healthcare Series Database 2.0 DrugDex Evaluation: Dextroamphetamine.
8. Micromedix Healthcare Series Database 2.0 DrugDex Evaluation: Dexmethylphenidate.
9. Micromedix Healthcare Series Database 2.0 DrugDex Evaluation:
Dextroamphetamine/Amphetamine.
10. Adderall Prescribing Information. Shire Pharmaceuticals. Reference ID: 4036383. Revised date
January 2017. Accessed December 20, 2021.
11. Dexedrine Prescribing Information. GlaxoSmithKline. Revised date February 2018. Accessed
December 20, 2021.
12. Kline MD, Lewi. Clinical presentation and diagnosis of obstructive sleep apnea in adults.
UpToDate. Literature review current Nov 2021. Accessed December 20, 2021.
13. Kryger MD FRCPS, Meir H, Malhotra MD, Atul. Management of obstructive sleep apnea in
adults. UpToDate. Literature review current through Nov 2021. Accessed December 20, 2021.
- ~~14. OAR 410-141-3855(15)~~
- ~~15. 42 USC 1396w-3a~~

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