


Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	Submission Date: 11/2020
Policy Number: PHW.PDL.007	Effective Date: 01/05/2021 Revision Date: 11/2020
Policy Name: Stimulants and Related Agents	
<p>Type of Submission – <u>Check all that apply:</u></p> <p> <input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review - No Revisions <input checked="" type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i> </p>	
<p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any changes or clarifying information for the policy below:</p> <p>Q1 2021: policy revised according to DHS revisions effective 01/05/2021.</p>	
<p>Name of Authorized Individual (Please type or print):</p> <p>Auren Weinberg, MD</p>	<p>Signature of Authorized Individual:</p> 

Clinical Policy: Stimulants and Related Agents

Reference Number: PHW.PDL.007

Effective Date: 01/01/2020

Last Review Date: 11/2020

[Revision Log](#)

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Stimulants and Related Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Stimulants and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Stimulants and Related Agents that meet the following conditions must be prior authorized.

1. A non-preferred Stimulants and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Stimulants and Related Agents at: <https://papdl.com/preferred-drug-list>.
2. A Stimulants and Related Agent with a prescribed quantity that exceeds the quantity limit.
3. A Stimulants and Related Agent for a beneficiary under 4 years of age.
4. A prescription for an analeptic Stimulants and Related Agent (e.g., armodafinil, modafinil, etc.).
5. A Stimulants and Related Agent when there is a record of a recent paid claim for another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) (therapeutic duplication). EXCEPTIONS: Intuniv (guanfacine ER), Kapvay (clonidine ER), an analeptic Stimulants and Related Agent.
6. A Stimulants and Related Agent when prescribed for a beneficiary 18 years of age or older. EXCEPTION: an analeptic Stimulants and Related Agent.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Stimulants and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Stimulants and Related Agent, except an analeptic agent, one of the following:
 - a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Stimulants and Related Agents approved or medically accepted for the beneficiary's diagnosis
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Stimulants and Related Agent;

AND

2. For an analeptic Stimulants and Related Agent, all of the following:
 - a. Is not receiving concurrent treatment with sedative hypnotics;
 - b. Is prescribed the analeptic Stimulants and Related Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication;
 - c. For the treatment of narcolepsy and shift work sleep disorder, has a diagnosis confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders);
 - d. For the treatment of obstructive sleep apnea/hypopnea syndrome (OSAHS), has both of the following:
 - i. A diagnosis of OSAHS confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders);
 - ii. A history of therapeutic failure of continuous positive airway pressure (CPAP) to resolve excessive daytime sleepiness (documented by either Epworth Sleepiness Scale greater than 10 or multiple sleep latency test (MSLT) less than 8 minutes) with documented compliance to CPAP treatment or, if the beneficiary has a medical reason CPAP cannot be used, therapeutic failure of an oral appliance for OSAHS;
 - e. For the treatment of multiple sclerosis-related fatigue, is receiving treatment for multiple sclerosis or, if not being treated, the medical record documents the rationale for the beneficiary not being treated;
 - f. For a non-preferred analeptic Stimulants and Related Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred analeptic Stimulants and Related Agents approved or medically accepted for the beneficiary's diagnosis;

AND

3. For a beneficiary under 4 years of age, all of the following:
 - a. Is prescribed the Stimulants and Related Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
 - b. Is being prescribed the medication by or in consultation with one of the following:
 - i. Pediatric neurologist,
 - ii. Child and adolescent psychiatrist,
 - iii. Child development pediatrician,
 - c. Has chart-documented evidence of a comprehensive evaluation by or in consultation with a specialist listed above;

AND

4. For a beneficiary 18 years of age or older, all of the following:
 - a. Is prescribed the Stimulants and Related Agent for an indication that is included in the FDA-approved package labeling OR a medically accepted indication,
 - b. For the treatment of attention deficit hyperactivity disorder (ADHD), has a diagnosis of ADHD as documented by a history consistent with the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria,
 - c. For the treatment of moderate to severe binge eating disorder, all of the following:
 - i. Has a diagnosis documented by a history that is consistent with the current DSM criteria,
 - ii. In the absence of a diagnosis of ADHD or attention deficit disorder (ADD), has a documented history of therapeutic failure, contraindication, or intolerance to selective serotonin reuptake inhibitors or topiramate,
 - iii. Has documentation of a referral for cognitive behavioral therapy or other psychotherapy,
 - d. For the treatment of narcolepsy, has the diagnosis confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders),
 - e. For a Stimulant Agent, **all** of the following:

- i. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,
 - ii. Has documentation that the beneficiary has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,
 - iii. Has documentation that the prescriber or prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program for the beneficiary's controlled substance prescription history,
- f. For a Stimulant Agent for a beneficiary with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances;

AND

5. For therapeutic duplication, one of the following:
- a. Is being transitioned to another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) with the intent of discontinuing one of the medications
 - b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested;

AND

6. If a prescription for a Stimulants and Related Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A STIMULANTS AND RELATED AGENT: The determination of medical necessity of a request for renewal of a prior authorization for a Stimulants and Related Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication;
AND
2. For therapeutic duplication, **one** of the following:

- a. Is being transitioned to another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) with the intent of discontinuing one of the medications
- b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested;

AND

3. If a prescription for a Stimulants and Related Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Stimulants and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

All requests for prior authorization of a prescription for a Stimulants and Related Agent for a Medical Assistance beneficiary under 4 years of age will be automatically forwarded to a physician reviewer (a psychiatrist) for a medical necessity determination. The physician reviewer (a psychiatrist) will consider the guidelines in Section B. above and will approve the request when, in the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

D. Approval Duration: 12 months

E. References:

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7. Kessler RC, et.al. Patterns and predictors of ADHD persistence into adulthood: Results from the National Comorbidity Survey Replication. *Biological Psychiatry*, 2005 June 1; 57(11): 1442-1451.
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10. National Institute on Drug Abuse Stimulant ADHD Medications: Methylphenidate and Amphetamines, June 2009.
11. Fact Sheet: Office of the National Drug Control Policy, Prescription Drugs: Weighing the Benefits and the Risks, December 2010.
12. Qaseem A, et.al. Management of Obstructive Sleep Apnea in Adults: A Clinical Practice Guideline From the American College of Physicians. *Annals of Internal Medicine*. 2013;159:471–483.
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14. Chevrin RD, et.al. Approach to the patient with excessive daytime sleepiness. UpToDate. Accessed January 23, 2020.
15. Satela, MJ. International Classification of Sleep Disorders-Third Edition Highlights and Modifications. *CHEST* 2014; 146(5): 1387–1394.
16. Kapur, VK. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *Journal of Clinical Sleep Medicine*. 2017;13(3):479–504.
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19. Expert Opinion Paper. National Clinical Advisory Board of the National Multiple Sclerosis Society. Management of MS-Related Fatigue. 2006.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021	11/2020