Clinical Policy: Stimulants and Related Agents

Reference Number: PHW.PDL.007
Effective Date: 01/01/2020
Last Review Date: 11/2024

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 PA Health & 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.

2. A Stimulants and Related Agent with a prescribed quantity that exceeds the quantity limit.

3. A Stimulants and Related Agent for a member 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 member 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 member:

1. For a request for Evekeo (amphetamine) for the treatment of obesity, see PHW.PDL.750 Obesity Treatment Agents; OR

2. 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 member's diagnosis,

    b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Stimulants and Related Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

    AND

3. 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 member 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 member 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 member's diagnosis;

AND

4. For a member 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

5. For a member 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, **both** 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 member has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,

f. For a Stimulant Agent for a member 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

6. 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

7. 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 PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member 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 member, 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 member:

1. Has documentation of a positive clinical response to the medication;
   AND

2. For a non-preferred Stimulants and Related Agent with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or

a contraindication or an intolerance to the preferred therapeutically equivalent generic, that would not be expected to occur with the requested medication; **AND**

3. For a non-preferred analeptic Stimulants and Related Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred analeptic Stimulants and Related Agents approved or medically accepted for the member's diagnosis; **AND**

4. 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

5. 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 member 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 member, 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 member.

All requests for prior authorization of a prescription for a Stimulants and Related Agent for a Medical Assistance member 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 member.

D. **Approval Duration: 12 months**

E. References:

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10. National Institute on Drug Abuse Stimulant ADHD Medications: Methylphenidate and Amphetamines, June 2009.
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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
Q1 2023: policy revised according to DHS revisions effective 01/09/2023	10/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025: policy revised according to DHS revisions effective 01/06/2025.	11/2024