

<b>ISSUE DATE</b>  November 16, 2020	<b>EFFECTIVE DATE</b>  January 5, 2021	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Stimulants and Related Agents – Pharmacy Services		<b>BY</b>   Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISE to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISE-Enrollment.aspx>.

**PURPOSE:**

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Stimulants and Related Agents submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Stimulants and Related Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Stimulants and Related Agents to the appropriate managed care organization.

*01-20-44	09-20-43	27-20-39	33-20-40
02-20-37	11-20-37	30-20-36	
03-20-37	14-20-38	31-20-44	
08-20-47	24-20-37	32-20-36	

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

**BACKGROUND:**

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

**DISCUSSION:**

During the August 12, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Stimulants and Related Agents:

- Address the U.S. Food and Drug Administration approval of new analeptic agents in the class and reflect the most current consensus treatment guidelines;
- Clarify when prior authorization is required for therapeutic duplication;
- Remove the guideline for a therapeutic trial of methylphenidate for a diagnosis of multiple sclerosis-related fatigue;
- Remove the guidelines for the determination of medical necessity of a request for renewal of a prescription for lisdexamfetamine for a diagnosis of moderate to severe binge eating disorder;
- Add a guideline for the determination of medical necessity of a request for renewal for a prescription for a Stimulant and Related Agent; and
- Clarify that automated prior authorization does not apply to analeptic Stimulants and Related Agents.

The revisions to the guidelines to determine medical necessity of Stimulants and Related Agents, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Stimulants and Related Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Stimulants and Related Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

**RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I  
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II  
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**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. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.
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) in the Point-of-Sale Online Claims Adjudication System (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**

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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,

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- 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:

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- 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

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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. Automated Prior Authorization

Prior authorization of a prescription for a non-preferred Stimulants and Related Agent with a quantity that does not exceed the quantity limit established by the Department will be automatically approved when the Point-of-Sale Online Claims Adjudication System verifies a record of a paid claim(s) within 180 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

Automated prior authorization approvals do not apply to the following:

1. A prescription for an analeptic Stimulants and Related Agent.
2. A prescription for a Stimulants and Related Agent for a beneficiary under 4 years of age.
3. A prescription for a Stimulants and Related Agent for a beneficiary 18 years of age or older.
4. Therapeutic duplication.

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