


ISSUE DATE September 11, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Stimulants and Related Agents – Pharmacy Services		BY  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:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 and providing services in the Fee-for-Service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Stimulants and Related Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T)

*01-19-64	09-19-60	27-19-58	33-19-60
02-19-58	11-19-57	30-19-56	
03-19-57	14-19-56	31-19-63	
08-19-66	24-19-58	32-19-56	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>
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Committee reviews published peer-reviewed clinical literature and makes recommendations relating to 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 June 21, 2019, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Stimulants and Related Agents:

- Revise the guidelines for Provigil (modafinil) and Nuvigil (armodafinil) when prescribed for obstructive sleep apnea/hypopnea syndrome to clarify the type of diagnostic testing used to determine the beneficiary's respiratory disturbance index and to allow for treatment with an oral appliance as a possible alternative to continuous positive airway pressure;
- Add a guideline for Provigil (modafinil) and Nuvigil (armodafinil) to recognize other diagnoses indicated in the U.S. Food and Drug Administration-approved package labeling or medically accepted indications;
- Add a guideline for Stimulant Agents that beneficiaries 18 years of age and older are assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider and have documentation that the beneficiary has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction, to align with guidelines to determine medical necessity for other controlled substances; and
- Remove the Stimulant Agents guideline for enrollment and active participation in a substance dependency treatment program and compliance with the substance dependency treatment program for beneficiaries 18 years of age and older with a history of comorbid substance dependency, abuse, or diversion.

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

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

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

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

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 Stimulant 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 Stimulant 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: www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.
3. A Stimulant and Related Agent for a beneficiary under 4 years of age.
4. A prescription for armodafinil or modafinil.
5. A Stimulant and Related Agent when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in the Department's Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication). EXCEPTION: Intuniv (guanfacine ER), Nuvigil (armodafinil), and Provigil (modafinil).
6. A Stimulant and Related Agent when prescribed for a beneficiary 18 years of age or older. EXCEPTION: Provigil (modafinil) and Nuvigil (armodafinil).

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 agent containing armodafinil or modafinil, **one** of the following:
 - a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Stimulants and Related Agents
 - b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Stimulants and Related Agent;

AND

2. For a non-preferred Stimulants and Related Agent containing armodafinil or modafinil, has a history of therapeutic failure, contraindication, or intolerance of the preferred Stimulants and Related Agents containing armodafinil or modafinil; **AND**

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3. For modafinil and armodafinil, **both** of the following:
 - a. Is not receiving concurrent treatment with sedative hypnotics
 - b. Has a diagnosis of **one** of the following:
 - i. Narcolepsy confirmed by an overnight polysomnogram (PSG) followed by a multiple sleep latency test (MSLT),
 - ii. Obstructive sleep apnea/hypopnea syndrome (OSAHS) documented by **both** of the following:
 - a) An overnight PSG with a respiratory disturbance index of greater than 5 per hour
 - b) Therapeutic failure of continuous positive airway pressure (CPAP) to resolve excessive daytime sleepiness (documented by either Epworth Sleepiness Scale greater than 10 or MSLT less than 6 minutes) with documented compliance to CPAP treatment or, if beneficiary has a medical reason CPAP can not be used, therapeutic failure of an oral appliance for OSAHS,
 - iii. Shift work sleep disorder as documented by **both** of the following:
 - a) The beneficiary's recurring work schedule for one (1) month or longer
 - b) Shift work that results in sleepiness on the job or insomnia at home that interferes with activities of daily living,
 - iv. Multiple sclerosis-related fatigue with **both** of the following:
 - a) Is receiving treatment for multiple sclerosis or, if not being treated, the medical record documents the rationale for the beneficiary not being treated
 - b) Has a history of therapeutic failure, contraindication, or intolerance to methylphenidate at maximum tolerated doses,
 - v. Another diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling or medically accepted indication;

AND

4. For children under 4 years of age, **all** of the following:
 - a. Has a diagnosis of **one** of the following:
 - i. Attention deficit hyperactivity disorder (ADHD),
 - ii. Attention deficit disorder (ADD),
 - iii. Brain injury,

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- iv. Autism,
- 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 beneficiaries 18 years of age and older, **all** of the following:
 - a. **One** of the following:
 - i. For a Stimulants and Related Agent, **one** of the following:
 - a) Has a diagnosis of ADHD as documented by a history consistent with the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria
 - b) Has a medically accepted indication,
 - ii. For lisdexamfetamine when prescribed for a diagnosis of moderate to severe binge eating disorder, **all** of the following:
 - a) Has a diagnosis documented by a history that is consistent with the current DSM criteria,
 - b) In the absence of a diagnosis of ADHD or ADD, has a documented history of therapeutic failure, contraindication, or intolerance to selective serotonin reuptake inhibitors or topiramate,
 - c) Has documentation of a referral for cognitive behavioral therapy or other psychotherapy,
 - iii. For a Stimulant Agent, when prescribed for a diagnosis of narcolepsy, has the diagnosis confirmed by an overnight PSG followed by a MSLT,
 - b. 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,

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- 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,

- c. 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, tramadol, and carisoprodol) that is consistent with prescribed controlled substances;

AND

- 6. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to, or tapered from, a drug in the same class
 - 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 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 LISDEXAMFETAMINE FOR A DIAGNOSIS OF MODERATE TO SEVERE BINGE EATING DISORDER, the determination of medical necessity of a request for renewal of a prior authorization for lisdexamfetamine that was previously approved will take into account whether the beneficiary had a reduction in binge eating.

C. 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 On-Line 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:

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

D. 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.

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8. Kessler RC, et.al. The prevalence and correlates of adult ADHD in the United States: Results from the National Comorbidity Survey Replication. *American Journal of Psychiatry*, 2006; 163: 716-723.
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