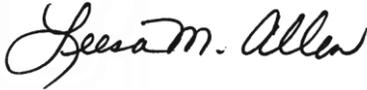




ISSUE DATE January 6, 2016	EFFECTIVE DATE January 20, 2016	NUMBER *See below
SUBJECT Prior Authorization of Stimulants and Related Agents - Pharmacy Service		BY  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers (including all associated service locations - 13 digits) who enrolled on or before **March 25, 2011** must revalidate their enrollment information no later than **March 24, 2016**. New enrollment application including all revalidation requirements may be found at http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994. Please send in your application(s) as soon as possible.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include instructions on how to request prior authorization of prescriptions for Stimulants and Related Agents, including the type of medical information needed to evaluate requests for medical necessity.

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 (FFS) delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to 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, and classes of drugs to be added to or deleted from the PDL. The P&T Committee also recommends new guidelines or

*01-16-05	09-16-05	27-16-05	
02-16-05	11-16-05	30-16-05	
03-16-05	14-16-05	31-16-05	
08-16-05	24-16-05	32-16-05	33-16-05

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 Web site at
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>

modifications to existing guidelines to evaluate requests for prior authorization of prescriptions for medical necessity.

DISCUSSION:

During the November 3, 2015 meeting, the P&T Committee recommended that the Department update the guidelines to determine medical necessity of Stimulants and Related Agents to include Vyvanse (lisdexamfetamine dimesylate) which recently received Food and Drug Administration (FDA) approval for treatment of moderate to severe binge eating disorder. At the recommendation of the Committee, the guidelines to determine medical necessity of Vyvanse were developed in consultation with an independent medical specialist and subsequently approved by the Committee. The recommended guidelines were then subject to public review and comment and approved for implementation by the Department. The revised clinical review guidelines to determine the medical necessity of Stimulants and Related Agents are included in the attached updated provider handbook pages.

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 chapters 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

SECTION II
Stimulants and Related Agents

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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 prescription for a non-preferred Stimulant and Related Agent. See Preferred Drug List (PDL) for the list of preferred Stimulants and Related Agents at:
www.providersynergies.com/services/documents/PAM_PDL.pdf
2. A prescription for a preferred Stimulant and Related Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:
http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf
3. A prescription for a preferred or a non-preferred Stimulant and Related Agent for a recipient under 4 years of age
4. A prescription for 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, Nuvigil and Provigil
5. A prescription for a preferred or non-preferred Stimulant and Related Agent for a recipient 18 years of age or older.
EXCEPTION: Provigil and Nuvigil

GRANDFATHER PROVISION – The Department will grandfather prescriptions for non-preferred Stimulants and Related Agents within quantity limits when the PROMISE Point-Of-Sale On-Line Claims Adjudication System verifies that the recipient has a record of a paid claim for a non-preferred Stimulant and Related Agent within the past 90 days from the date of service of the new claim. If the recipient has a record of a paid claim for a non-preferred Stimulant and Related Agent, a prescription or a refill for the same Stimulant and Related Agent within the quantity limits will be automatically approved.

Grandfathering does not apply to prescriptions for either a preferred or non-preferred Stimulant and Related Agent when prescribed for a

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recipient under 4 years of age or 18 years of age or older, or that are considered to be duplicate therapy.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Stimulant and Related Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Provigil (modafinil) and Nuvigil (armodafinil) – Whether the recipient:
 - a. Is not receiving concurrent treatment with sedative hypnotics

AND

- b. Has a diagnosis of:
 - i. Narcolepsy confirmed by an overnight polysomnogram (PSG) followed by a:
 - a) A multiple sleep latency test (MSLT)

OR

- ii. Obstructive sleep apnea/hypopnea syndrome (OSAHS) documented by a Respiratory Disturbance Index (RDI) of greater than 5 per hour

AND

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 6 minutes)

OR

- c. Shift work sleep disorder (SWSD) as documented by:

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- i. Recipient's recurring work schedule for one (1) month or longer

AND

- ii. Shift work which results in sleepiness on the job or insomnia at home that interferes with activities of daily living

OR

- d. Has a diagnosis of multiple sclerosis and fatigue associated with multiple sclerosis **AND**

- i. Is receiving treatment for multiple sclerosis

AND

- ii. Tried and failed methylphenidate at maximum dosing

AND

- 2. For Nuvigil - Whether the recipient has a history of therapeutic failure, contraindication or intolerance to Provigil
- 3. For Intuniv, whether the recipient has a documented history of therapeutic failure of Guanfacine
- 4. For all other non-preferred Stimulants and Related Agents, whether the recipient has a history of therapeutic failure of the preferred Stimulants and Related Agents.
- 5. For children under 4 years of age - Whether the MA recipient
 - a. Has a diagnosis of:
 - i. Attention Deficit Hyperactivity Disorder (ADHD), **OR**
 - ii. Attention Deficit Disorder (ADD), **OR**
 - iii. Brain injury, **OR**
 - iv. Autism

AND

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- b. Is being prescribed the medication by an appropriate specialist or in consultation with a:
 - i. Pediatric Neurologist, **OR**
 - ii. Child and Adolescent Psychiatrist. **OR**
 - iii. Child Development Pediatrician

AND

- c. Has chart documented evidence of a comprehensive evaluation by the prescriber or in conjunction with a specialist listed above
6. For therapeutic duplication, whether:
- a. The recipient is being titrated to, or tapered from, a drug in the same class

OR

- b. Supporting peer reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested
7. For a preferred or non-preferred Stimulant and Related Agent for recipients 18 years of age and older:
- a. For a Stimulant and Related Agent, whether the recipient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) as documented by a history consistent with the most current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria
 - b. For lisdexamfetamine when prescribed for a diagnosis of moderate to severe binge eating disorder, whether :
 - i. The diagnosis is documented by a history that is consistent with the most current DSM criteria

AND

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- ii. In the absence of a diagnosis of ADHD or attention deficit disorder, the recipient has a documented history of therapeutic failure, contraindication or intolerance to SSRIs or topiramate

AND

- iii. The recipient has documentation of a referral for cognitive behavioral therapy or other psychotherapy

- c. For a Stimulant Agent, whether the recipient has a diagnosis of narcolepsy as confirmed by:

- i. A sleep study followed by a multiple sleep latency test

AND

- ii. A history consistent with narcolepsy

AND

- d. For a Stimulant Agent for a recipient with a history of co-morbid substance dependency, abuse or diversion, whether the recipient:

- i. Is enrolled and actively participating in a substance dependency treatment program

AND

- ii. Demonstrates compliance with the substance dependency treatment program as documented by a recent urine drug screen that tests negative for benzodiazepines, opiates and illicit drugs

OR

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- iii. Has a documented history of recovery and a recent negative urine drug screen for benzodiazepines, opiates and illicit drugs

OR

- 8. Whether the recipient 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 recipient.
- 9. In evaluating a request for a renewal of prior authorization of a prescription for lisdexamfetamine for a diagnosis of moderate to severe binge eating disorder, the determination of whether the requested prescription is medically necessary will take into account whether the recipient had a reduction in binge eating

C. Automated Prior Authorization Approvals

Prior authorization of a prescription for a non-preferred Stimulant and Related Agent in a quantity that does not exceed the quantity limit will be automatically approved when the PROMISe Point-of-Sale On-Line Claims Adjudication System verifies a record of 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 a preferred or non-preferred Stimulant and Related Agent with a prescribed quantity that exceeds the quantity limit
- 2. A prescription for a preferred or a non-preferred Stimulant and Related Agent for a recipient under 4 years of age
- 3. Therapeutic duplication
- 4. A prescription for a preferred or non-preferred Stimulant and Related Agent for a recipient 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 the request for a prescription for a Stimulant 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

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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 recipient.

All requests for prior authorization of a prescription for a Stimulant and Related Agent for a MA recipient 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 recipient.

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