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: 10/01/2019**
Policy Number: PHW.PDL.007	**Effective Date: 01/01/2020** **Revision Date: 10/01/2019**
Policy Name: Stimulants and Related Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy created.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Stimulants and Related Agents

Reference Number: PHW.PDL.007
Effective Date: 01/01/2020
Last Review Date: 10/01/2019

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 Stimulant and Related Agent.
2. A Stimulant and Related Agent with a prescribed quantity that exceeds the quantity limit.
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 (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**

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 cannot 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,
      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,
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 PA.CP.PMN.59 Quantity Limit Override.

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. 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:

1. Greenhill LL. The use of Psychotropic Medication in Preschoolers: Indications, Safety and Efficacy. Can J Psychiatry 1998; 43:576-581.
2. Diller LH. Lessons from Three Year Olds. Developmental and Behavioral Pediatrics. 2002; 23:S10-S12.
3. American Academy of Pediatrics. Clinical Practice Guideline: Treatment of the School-Aged Child with Attention-Deficit/ Hyperactivity Disorder. Pediatrics 2001; 108:1033-1044
4. American Academy of Child and Adolescent Psychiatry: Practice Parameter for the Assessment and Treatment of Children and Adolescents with attention-Deficit/Hyperactivity Disorder. 2007.
5. Walter, H, Bukstein, O. "AACAP Practice Parameter for the Assessment and Treatment of Children and Adolescents With Attention-Deficit/ Hyperactivity Disorder" Journal of the American Academy of Child and Adolescent Psychiatry. 2007; 46: 894-921.
6. Scahill L, Chappell PB, Kim YS et al. "A placebo-controlled study of guanfacine in the treatment of children with tic disorders and attention deficit hyperactivity disorder" American Journal of Psychiatry. 2001; 158: 1067-1074.
7. Intuniv™ Package Insert, Shire Pharmaceuticals August 2009.
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.

9. 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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020