Gateway Health It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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 for a beneficiary under 4 years of age.

3. A prescription for an analeptic Stimulants and Related Agent (e.g., armodafinil, modafinil, etc.).

4. 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.

5. 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

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,

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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,

   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,

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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:

   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;

   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

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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;

   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

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.

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STIMULANTS AND RELATED AGENTS – PROVIGIL / NUVIGIL / SUNOSI / WAKIX PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	
Directions:	Quantity:	Refills:
Diagnosis (*submit documentation*):	Dx code (required):	
Will the beneficiary receive concurrent treatment with a sedative/hypnotic medication(s)?	☐Yes ☐No	*Submit documentation of current complete medication list.*

INITIAL Requests

For a non-preferred drug: Does the beneficiary have a history of trial and failure, contraindication, or intolerance to the preferred drugs in this class that are FDA-approved or medically accepted for the treatment of the beneficiary's condition? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes ☐No	*Submit documentation.*

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐For treatment of narcolepsy:
- ☐Diagnosis is consistent with current International Classification of Sleep Disorders criteria (e.g., MSLT, overnight PSG, hypocretin-1 concentration, clinical assessment, etc.)

☐For treatment of shift work sleep disorder:
- ☐Diagnosis is consistent with current International Classification of Sleep Disorders criteria (e.g., shift work schedule, sleep log & actigraphy monitoring, other causes ruled out, clinical assessment, etc.)

☐For treatment of obstructive sleep apnea/hypopnea syndrome:
- ☐Diagnosis is consistent with current International Classification of Sleep Disorders criteria (e.g., overnight PSG, out-of-center sleep testing, associated medical or psychiatric disorders, clinical assessment, etc.)
- ☐Tried and failed continuous positive airway pressure (CPAP) while adherent to treatment to resolve daytime sleepiness demonstrated by:
  - ☐Epworth Sleepiness Scale >10
  - ☐Multiple sleep latency test (MSLT) <8 minutes
- ☐Cannot use CPAP – reason: _____
  - ☐Tried and failed an oral appliance for OSAHS to resolve daytime sleepiness

☐For treatment of fatigue related to multiple sclerosis:
- ☐Is currently receiving treatment for MS
- ☐Is not receiving treatment for MS – reason: _____

RENEWAL Requests

Has the beneficiary experienced a positive clinical response since starting the requested medication? *Submit documentation.*	☐Yes ☐No

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date:

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STIMULANTS AND RELATED AGENTS PRIOR AUTHORIZATION FORM (*form effective 01/05/2021*)

☐New request ☐Renewal request	total # of pgs: _____	Prescriber name/specialty:	
Name/phone of office contact:		State license #:	NPI:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form (tablet, ODT, suspension, etc.):	
Directions:		Quantity:	# months requested:
Diagnosis *(submit documentation)*:		Diagnosis code (*required*):	

INITIAL Requests

Has the beneficiary been taking the requested medication within the past 90 days?	☐Yes ☐No *Submit documentation of drug regimen and clinical response.*
For a non-preferred drug: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred drugs in this class that are approved or medically accepted for treatment of the beneficiary's condition? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*	☐Yes ☐No *Submit documentation.*

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐For a child <4 years of age:
- ☐Is prescribed the requested medication AND had a comprehensive evaluation by or in consultation with one of the following specialists:
  - ☐pediatric neurologist ☐child/adolescent psychiatrist ☐child development pediatrician

☐**For a beneficiary ≥18 years of age:**
- ☐For the treatment of ADHD: ☐Has a diagnosis of ADHD that is consistent with current DSM criteria
- ☐For the treatment of narcolepsy: ☐Has a diagnosis of narcolepsy consistent with current International Classification of Sleep Disorders criteria (e.g., MSLT, overnight PSG, CSF hypocretin-1 concentration, clinical assessment)
- ☐For a diagnosis of binge eating disorder consistent with current DSM criteria:
  - ☐Tried and failed (or cannot try) SSRIs (unless beneficiary has comorbid ADD or ADHD)
  - ☐Tried and failed (or cannot try) topiramate (unless beneficiary has comorbid ADD or ADHD)
  - ☐Was referred for cognitive behavioral therapy or other psychotherapy
- ☐For a stimulant agent:
  - ☐Was assessed for potential risk of misuse, abuse, and/or addiction based on family and social history
  - ☐Was educated regarding the potential adverse effects of stimulants, including the risk of misuse, abuse, and addiction
  - ☐Has documentation that the provider checked the PDMP for the beneficiary's controlled substance prescription history
  - ☐For a beneficiary with a history of substance dependency, abuse, or diversion:
    - ☐Has results of a recent UDS for licit & illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances

RENEWAL Requests

Has the beneficiary experienced a positive clinical response since starting the requested medication?	☐Yes ☐No *Submit documentation.*

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: