DRUG DETERMINATION POLICY

Title: DDP-32 Sleep Disorder Agents

Effective Date: 6/28/23

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Health Plan covers the sleep disorder medications, Sunosi oral (solriamfetol) when prior authorization criteria are met. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of adverse effects, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. Obstructive Sleep Apnea [must meet all listed below]:

   A. Age: at least 18 years.

   B. Diagnosis and severity.

      1. Etiology: obstructive apneas, hypopneas or respiratory efforts related arousals.

      2. Symptoms: witnessed apnea; snoring; gasping/choking; excessive sleepiness not explained by other factors; non-refreshing sleep; sleep fragmentation; insomnia; morning headache(s); decreased concentration; memory loss; decreased libido; irritability.

   C. Polysomnography confirmation [must meet both listed below]:

      1. In conjunction with appropriate Positive Airway Pressure titration.

2. Apnea Hypopnea Index value [must meet one listed below]:

    a. With symptoms: At least five per hour in conjunction with symptoms of daytime sleepiness, loud snoring, witnessed apneas, or awakening due to gasping/choking.

    b. No symptoms: At least fifteen per hour without symptoms.

D. Other therapies - contraindicated, inadequate response after four-month trial or significant adverse effects to all pertinent categories listed below:

1. Central nervous system stimulants [must meet both listed below]:

    a. Modafinil: 100 to 200 mg per day (quantity limit of one per day).

    b. Armodafinil: 150 to 250 mg per day (quantity limit of one per day).

2. OSA with allergic rhinitis [must meet one listed below]:

    a. Nasal steroids.

3. Continuous Positive Airway Pressure [must meet both listed below]:

    a. Maximized therapy: used for over four hours per night for over 70 percent of the nights.

    b. Rule out CPA issues: mask fit, humidity, ramp, repair, need for alternative Positive Airway Pressure (PAP) modality, pressure leaks, or inadequate pressure.

E. Dosage regimen.

1. Sunosi oral (solriamfetol): 37.5mg per day (half 75mg tab); then, based on response and tolerability, may double the dose at least three-day intervals to a maximum dose of 150mg per day.

F. Approval.

1. Initial: six months.

2. Re-approval:

    a. Continue to meet criteria for obstructive sleep apnea.

    b. Duration: six months to one year.

II. Narcolepsy with or without cataplexy [must meet all listed below]:

A. Age. 7 to 64 years.

B. Prescriber: neurologist, psychiatrist, or sleep medicine specialist.

C. Narcolepsy type 1: narcolepsy with cataplexy [must meet all listed below]:

1. Diagnosis and severity [must meet both listed below]:

    a. Presence of excessive daytime sleepiness for more than three months.

    b. Cataplexy: loss of muscle tone in full consciousness triggered by emotions.

2. Multiple Sleep Latency Tests confirmation [must meet both listed below]:

    a. Sleep latency: less than eight minutes.

    b. Sleep-onset REM periods: demonstrated in at least two naps after at least six hours of sleep the night before.

D. Narcolepsy type 2 narcolepsy without catalepsy [must meet all listed below]:

1. Diagnosis and severity [must meet all listed below]:

    a. Presence of excessive daytime sleepiness for more than three months.

    b. Variable clinical course with improvement or even disappearance of the symptoms, the development of cataplexy, or a change to idiopathic hypersomnia:

2. Multiple Sleep Latency Tests confirmation [must meet all listed below]:

    a. Sleep latency: less than eight minutes.

    b. Sleep-onset REM periods: demonstrated in at least two naps after at least six hours of sleep the night before.

E. Other therapies: contraindicated, inadequate response after four months or significant adverse effects to each agent listed below:

1. Modafinil: 100 to 200mg per day (quantity limit of one per day).

2. Armodafinil: 150 to 250mg per day (quantity limit of one per day).

3. Methylphenidate or amphetamine analogue.

F. Dosage regimen.

1. Sunosi (solriamfetol): 75 mg per day, then based on response and tolerability, may double the dose at least three-day intervals to a maximum dose of 150 mg per day.

G. Approval.

1. Initial: six months.

2. Re-approval:

    a. Continue to meet criteria for Narcolepsy.

    b. Duration: six months to one year.

III. Exclusions:

A. Hypersomnia better explained by other factors (see Appendix I).

1. Other sleep disorders: insufficient sleep syndrome, poor sleep hygiene.

2. Other general disorders/conditions: neurological disorder, mental disorder, thyroid disorder, genetic disorder, inflammatory conditions.

3. Substance: sedating medication use or substance use disorder.

B. Excluded Drugs: Xyrem (sodium oxybate), Xywav (oxybate salts), Wakix (pitolisant).

1. All preferred medications are contraindicated, inadequate response after a four-month trial, or significant adverse effects.

a. Formulary medications include CNS stimulants (e.g., methylphenidate), modafinil, armodafinil, and Sunosi (solriamfetol).

C. Inappropriate medication use.

1. Food and Drug Administration (FDA) approval status [must meet one listed below]:

a. Non-FDA approved: product, indication, and/or dosage regimen without compendium support

2. Place in therapy: sequence of therapy not supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

4.0 Coding:

None.

5.0 References, Citations & Resources:

1. Narcolepsy: Clinical approach to etiology, diagnosis & treatment. Reviews in Neurological Disease 2011;8 (3-4) ;e97-e106.
2. Optimal treatment of obstructive sleep apnea & excessive sleepiness. Adv. Ther 2009;26(3):295-312.
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Sunosi, Xyrem accessed May 2021.
4. UpToDate [Internet] Accessed January 2020. Available from: http://www.uptodate.com/contents/.
   - Management of obstructive sleep apnea in adults.
   - Overview of obstructive sleep apnea in adults.
5. Central Disorders of hypersomnolence: Focus on the narcolepsies and idiopathic hypersomnia.
6. Screening for Obstructive Sleep Apnea in Adults: An Evidence Review for the U.S. Preventive Services Task Force [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017 Jan.
7. Clinical Guidelines for evaluating, managing, and long-term care of obstructive sleep apnea in adults.
8. Journal of Clinical Sleep Medicine 2008;5(3):263-276.
9. Medical therapy for obstructive sleep apnea: A review by the medical therapy for obstructive sleep apnea task force of the standard of practice committee of the American Academy of Sleep Medicine. SLEEP 2006;29(8):1036-1044.
10. Narcolepsy and other central hypersomnias. Continuum 2017;23(4):989-1004.
11. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med 2021; 17:1895.
12. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med 2021; 17:1881.
13. European guideline and expert statements on the management of narcolepsy in adults and children. Eur J Neurol 2021; 28:2815

6.0 Appendices:

See pages 6-8.

7.0 Revision History:

Original Effective Date: 07/21/2004

Next Review Date:

Revision Date	Reason for Revision
8/19	Moved to new format; moved dosing, filled in missing criteria under MSLT, replaced abbreviations, clarified dosing
1/20	Off cycle review, changed title; deleted Provigil, Nuvigil from authorization and now are other therapies; added Sunosi and Xyrem; added age and prescriber to narcolepsy criteria.
11/20	Off cycle review, excluded Xyrem, Xywav, added inappropriate medication use under exclusions, approved by P&T Committee 12/9/20
5/21	Annual review clarified criteria instructions and sleep-onset REM periods; eliminated or replaced abbreviations
4/22	Annual review for May workgroup and the June P and T committee; corrected numbering added compendium to appropriate use
4/23	Annual review; added references, clarified inappropriate use

Appendix I: Differential Diagnosis of Excessive Daytime Sleepiness

Insufficient Sleep	
Sleep deprivation	
Environmental intrusions	
Sleep Disorders	
Obstructive sleep apnea (OSA)	
Central sleep apnea	
Sleep related hypoventilation of hypoxemia	
Central disorders of hyper somnolence:	• Narcolepsy (1 or 2). • Kleine-Levine syndrome. • Idiopathic hypersomnia
Circadian rhythm sleep-wake disorders	• Delayed sleep phase disorder. • Advance sleep phase disorder. • Jet lag, • Shift work
Restless legs syndrome	
Other Neurological Disorders	
Neurodegenerative disease	• Parkinson's disease • Dementia with Lewy bodies • Alzheimer's disease • Multiple system atrophy
Myotonic dystrophy	
Multiple Sclerosis (MS)	
Amyotrophic Lateral Sclerosis	
Structural lesions affecting thalamus, hypothalamus or brainstem	
Traumatic Brain injury	
Encephalitis lethargica	
Cerebral trypanosomiasis	
Medical & Genetic Disorders	
Hypothyroidism	
Obesity	
End-stage renal disease	
Adrenal insufficiency	
Hepatic encephalopathy	
Niemann-Pick Type C	
Prader-Willi syndrome	
Psychiatric Disorders	
Depression	
Anxiety	
Substance abuse: alcohol, narcotics. Rx opioids. stimulant withdrawal	
Psychogenic sleepiness	
Medications	
Benzodiazepines, non-benzodiazepine sedatives, antipsychotics, opioid analgesics, beta blockers (lipophilic), barbiturates, antihistamines, anticonvulsants, sedative antidepressants, muscle relaxers	

Appendix II: Definitions

Term	Definition
Apnea	Cessation of airflow for at least 10 seconds[8,275]
Hypopnea	Reduction in airflow by at least 30% for at least 10 seconds with decrease in oxygen saturation
Apnea-hypopnea index (AHI)[*]	Number of apnea and hypopnea events per hour of sleep
Obstructive sleep apnea (OSA)	
Mild[8,73]	AHI ≥5 to <15
Moderate[8,73]	AHI ≥15 to <30
Severe[8,73]	AHI ≥30
Obstructive sleep apnea syndrome	AHI ≥5 with evidence of daytime sleepiness[3,8,276]

* The respiratory disturbance index (RDI) is a similar measure to AHI, but it also includes the number of respiratory effort–related arousals per hour of sleep (in addition to apnea and hypopnea events).

Abbreviations: AHI=apnea-hypopnea index; OSA=obstructive sleep apnea; RDI=respiratory disturbance index.

Appendix III: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring	REMS
Sunosi oral (solriamfetol):	• Central Nervous System: headache (16%)	• Cardiovascular: blood pressure, heart rate	Not needed
Wakix (pitolisant)	• Central Nervous System: headache (18%)	• Renal and Hepatic Function	Not needed
Xyrem oral (sodium oxybate)	• Central Nervous System: confusion (3-17%), headache (16%), dizziness (6-15%) • Endocrine and Metabolic • Gastrointestinal: nausea (6-20%), vomiting (2-16%), weight loss (12%) • Genitourinary: urinary incontinence Z(3-18%)	• Central Nervous System: signs and symptoms of depression/suicidality, emergence of anxiety, confusion, thought disorders or behavioral abnormalities; drug abuse, misuse, and addiction	Patient medication guide