



## **Clinical Policy: Narcolepsy Agents (Armodafinil-Nuvigil, Modafinil-Provigil, Solriamfetol-Sunosi, Pitolisant-Wakix, Sodium Oxybate-Xyrem, Xywav)**

Reference Number: IN.CP.PMN.500

Effective Date: 03.02.20

Last Review Date: 01.21

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

The intent of the criteria is to promote prudent prescribing of agents for treatment of narcolepsy.

Armodafinil (Nuvigil<sup>®</sup>), Modafinil (Provigil<sup>®</sup>), and Solriamfetol (Sunosi<sup>™</sup>) are wakefulness-promoting agents.

Wakix<sup>®</sup> (pitolisant) is a selective histamine 3 (H<sub>3</sub>) receptor antagonist/inverse agonist.

Sodium oxybate (Xyrem<sup>®</sup>) is a central nervous system (CNS) depressant.

### **FDA Approved Indication(s)**

Nuvigil, and Provigil are indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA), narcolepsy, or shift work disorder (SWD).

Limitation(s) of use: In OSA, Nuvigil, and Provigil are indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Nuvigil, Provigil for excessive sleepiness.

Sunosi is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

Limitation(s) of use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.

Wakix is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

Xywav is indicated for treatment of Cataplexy in narcolepsy and excess daytime sleepiness (EDS).

Xyrem is indicated for the treatment of patients 7 years of age and older with:

- Cataplexy in narcolepsy

- Excessive daytime sleepiness (ED S) in narcolepsy

Limitation(s) of use: Xyrem may only be dispensed to patients enrolled in the Xyrem REMS Program.

**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 Managed Health Services that these Narcolepsy agents are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Nuvigil (must meet all):**

1. Diagnosis of one of the following:
  - a. Narcolepsy
  - b. Excessive Daytime Sleepiness
  - c. Obstructive Sleep Apnea/hypopnea (OSA) syndrome with residual excessive daytime sleepiness in conjunction with appropriate medical treatment
  - d. Shift Work Sleep (SWD) disorder
  - e. Bipolar Depression with standard of Care
2. Age  $\geq$  18 years
3. Dose does not exceed 250 mg per day

**Approval duration:**

**Medicaid-** 12 months

**B. Provigil (must meet all):**

1. Diagnosis of one of the following:
  - a. Narcolepsy
  - b. Excessive Daytime Sleepiness
  - c. Obstructive Sleep Apnea/hypopnea (OSA) syndrome
  - d. Shift Work Sleep (SWD) disorder
  - e. Attention Deficit Hyperactivity Disorder
  - f. Unipolar and Biopolar Depression
  - g. Depression-related fatigue
  - h. Sleep Deprivation
  - i. Steinert Myotonic Dystrophy Syndrome
2. Age  $\geq$  6 years
3. Dose does not exceed 400 mg per day

**Approval duration:**

**Medicaid-** 12 months

**C. Sunosi (must meet all):**

1. Age  $\geq$  18years
2. Diagnosis of one of the following:
  - a. Narcolepsy or
  - b. Obstructive Sleep Apnea/hypopnea (OSA) syndrome
3. If OSA, member needs a trial and failure of Modafinil or Armodafinil in the past year or medical justification for use
4. Dose does not exceed 150 mg per day

**Approval duration:**

**Medicaid-** 12 months

**D. Wakix (must meet all):**

1. Diagnosis of one of the following:
  - a. Narcolepsy
2. Age  $\geq$  18years
3. Dose does not exceed 35.6 mg (two 17.8 mg tablets) per day.

**Approval duration:**

**Medicaid-** 12 months

**E. Xyrem (must meet all):**

1. Age  $\geq$  7 years
2. Diagnosis of Narcolepsy with cataplexy and/or excessive daytime sleepiness OR  
Diagnosis of fibromyalgia
3. If diagnosis of fibromyalgia, evidence of previous trial and failure of the following or medical justification for use:
  - a. Amitriptyline
  - b. SNRIs
  - c. SSRIs
  - d. Anticonvulsants (gabapentin, pregabalin)
  - e. NSAIDs and acetaminophen
4. Dose does not exceed 9 grams per day (18 mL per day)

**Approval duration:**

**Medicaid-** 12 months

**F. Xywav (must meet all):**

1. Age  $\geq$  7 years
2. Diagnosis of Narcolepsy with cataplexy and/or excessive daytime sleepiness

**Approval duration:**

**Medicaid-** 12 months

**II. Continued Therapy**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed limits in section I:

**Approval duration:**

**Medicaid**– 12 months

**III. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CPAP: continuous positive airway pressure

FDA: Food and Drug Administration

EDS: excessive daytime sleepiness

OSA: obstructive sleep apnea

SWD: shift work disorder

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	03/02/2020	04/2020
Updated criteria for Sunosi and Xyrem to align with State	07/2020	
Added Xywav to policy	10/22/2020	
Q1 2021 Annual Review-no changes	01.21	01.21

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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