Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Wakefulness Agents

Effective: June 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Armodafinil and **modafinil** are oral wakefulness-promoting medications, FDA-approved to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder.

Sunosi (solriamfetol) is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Sunosi is not indicated to treat the underlying airway obstruction in obstructive sleep apnea.

Wakix (pitolisant) is a histamine-3 (H3) receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in patients 6 years of age and older with narcolepsy.

Xyrem (sodium oxybate) and **Xywav (calcium, magnesium, potassium, and sodium oxybates)** are central nervous system depressants indicated for cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. Xywav (calcium, magnesium, potassium, and sodium oxybates) is also indicated for the treatment of idiopathic hypersomnia (IH) in adults. Xyrem and Xywav are contraindicated in patients being treated with sedative hypnotics or alcohol. They are also contraindicated in patients with succinic semialdehyde dehydrogenase deficiency.

Clinical Guideline Coverage Criteria

Generic armodafinil and modafinil

The plan may authorize coverage of armodafinil or modafinil for patients when the following criteria are met:

1. Patient has documented diagnosis of excessive daytime sleepiness associated with one of the following medical conditions:
    a. Narcolepsy
    b. Idiopathic hypersomnia
    c. Obstructive sleep apnea/hypopnea syndrome
    d. Depression
    e. Multiple sclerosis
    f. Shift work disorder
    g. Chronic fatigue syndrome
    h. Organic brain disorder
    i. Parkinson's disease
    j. Cancer patient being treated with chemotherapy

Sunosi (solriamfetol)

The plan may authorize coverage of Sunosi (solriamfetol) for patients when all following criteria are met:

1. Patient is 18 years of age or older

AND

2. Prescribed by or in consultation with a neurologist or sleep specialist

AND

3. **ONE** of the following:
    a. **ALL** of the following:
        i. Patient has a documented diagnosis of **excessive daytime sleepiness associated with narcolepsy**
        ii. **ONE** of the following:
            1. **BOTH** of the following:
                a. Trial and failure, inadequate response, intolerance, or contraindication to modafinil OR armodafinil
                b. Trial and failure, inadequate response, intolerance, or contraindication to one stimulant medication (e.g., a methylphenidate-based or amphetamine-based medication)

OR

            2. The patient is new to the plan and has been stable on Sunosi for at least 2 months prior to enrollment, excluding the use of samples

OR

    b. **ALL** of the following:
        i. Patient has a documented diagnosis of **excessive daytime sleepiness associated with obstructive sleep apnea**
        ii. **ONE** of the following:
            1. **BOTH** of the following:
                a. Trial and failure, inadequate response, intolerance, or contraindication to modafinil OR armodafinil
                b. There is documentation that the underlying airway obstruction is being treated (i.e., continuous positive airway pressure (CPAP)) concurrently

OR

            2. **BOTH** of the following:
                a. The patient is new to the plan and has been stable on Sunosi for at least 2 months prior to enrollment, excluding the use of samples
                b. There is documentation that the underlying airway obstruction is being treated (i.e., continuous positive airway pressure (CPAP)) concurrently

Renewal Authorization for Sunosi (solriamfetol)

1. Documentation that patient experienced improvement from baseline based on reduction in daytime sleepiness

AND

2. For treatment of excessive daytime sleepiness associated with obstructive sleep apnea, there is documentation that patient is adherent to treatment(s) for the underlying airway obstruction (i.e., continuous positive airway pressure [CPAP])

Wakix (pitolisant)

The plan may authorize coverage of Wakix (pitolisant) for patients when all following criteria are met:

1. Patient is 6 years of age or older

AND

2. Prescribed by or in consultation with a neurologist or sleep specialist

AND

3. **ONE** of the following:
    a. Patient has a documented diagnosis of narcolepsy with cataplexy

OR

    b. **ALL** of the following:
        i. Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy
        ii. **ONE** of the following:
            1. For patients 18 years of age or older, **ONE** of the following:
                a. There is evidence of inadequate response, adverse reaction, or contraindication to **ALL** of the following:

i. Modafinil OR armodafinil
ii. Stimulant medication (e.g., a methylphenidate-based or amphetamine-based medication)
iii. Sunosi (solriamfetol)

OR

b. The patient is new to the plan and has been stable on Wakix for at least 2 months prior to enrollment, excluding the use of samples

OR

2. For patients 6 to 17 years of age, trial and failure, inadequate response, intolerance, or contraindication to one stimulant medication (e.g., a methylphenidate-based or amphetamine-based medication)

Renewal Authorization for Wakix (pitolisant)

1. Documentation that patient experienced improvement from baseline based on **ONE** of the following:
    a. Decrease in the frequency of cataplexy attacks
    b. Reduction in daytime sleepiness

Sodium Oxybate Containing Drugs

The plan may authorize coverage of **Xyrem** (sodium oxybate) or **Xywav** (calcium, magnesium, potassium, and sodium oxybates) for patients when **ALL** of the following criteria are met:

1. Patient is 7 years of age or older

AND

2. Prescribed by or in consultation with a neurologist or sleep specialist

AND

3. Documentation that the patient is not concurrently taking a sedative hypnotic (e.g., benzodiazepines, barbiturates, zolpidem, Z-drugs) as evidenced by paid claims history within the past 90 days, **OR** the provider attests that all hypnotic agents will be discontinued before initiating treatment with Xyrem or Xywav

AND

4. **ONE** of the following:
    a. Patient has a documented diagnosis of narcolepsy with cataplexy

    OR

    b. **ALL** of the following:
        i. Patient has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy
        ii. **ONE** of the following:
            1. For patients 18 years of age or older, there is evidence of inadequate response, adverse reaction, or contraindication to **ALL** of the following:
                a. Modafinil OR armodafinil
                b. Stimulant medication (e.g., a methylphenidate-based or amphetamine-based medication)
                c. Sunosi (solriamfetol)

            OR

            2. For patients 7 to 17 years of age, trial and failure, inadequate response, intolerance, or contraindication to one stimulant medication (e.g., a methylphenidate-based or amphetamine-based medication)

    OR

    c. The request is for Xywav and patient has a documented diagnosis of idiopathic hypersomnia

Renewal Authorization for Sodium Oxybate Containing Drugs

1. Documentation that the patient had an office visit and was reassessed for the condition within the past year and continued therapy continues to be considered medically necessary

AND

2. Patient is not concurrently using a sedative hypnotic (e.g., benzodiazepines, barbiturates, zolpidem, Z-drugs) as evidenced by paid claims history within the past 90 days

Limitations

1. Drugs for treatment of sleep disorders will not be authorized for non-medical conditions such as, but not limited to the following:
    - Working shift work (works night shift, etc.)
    - Generalized fatigue
    - Travel (jet lag, etc.)
    - Sleep-deprivation (i.e., military or academic use)
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
3. Duration of approval for Sunosi, Wakix, Xyrem, and Xywav is limited to 12 months.
4. Sodium oxybate containing drugs will not be approved in children less than 7 years of age.
5. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

None

References

1. Nuvigil (armodafinil) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; December 2022.
2. Provigil (modafinil) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc; December 2022.
3. Sunosi (solriamfetol) [prescribing information]. New York, New York: Axsome Therapeutics, Inc; June 2023.
4. Wakix (pitolisant) [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences LLC; February 2026.
5. Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc; July 2025.
6. Xywav (calcium, magnesium, potassium, and sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals Inc; July 2025.
7. Scammell, TE. Treatment of Narcolepsy in Adults. In: UpToDate, Eichler AF (ed), Waltham, MA. Accessed July 13, 2023.
8. Maski K, Trotti LM, Kotagal S, Robert Auger R, Rowley JA, Hashmi SD, Watson NF. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021 Sep 1;17(9):1881-1893.
9. Pepin JL. Evaluation and Management of Residual Sleepiness in Obstructive Sleep Apnea. In: UpToDate, Finlay G (ed), Waltham, MA. Accessed July 13, 2023.
10. Epstein LJ, Kristo D, Strollo PJ Jr, et al; Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009;5(3):263-276.
11. Chervin RD. Idiopathic hypersomnia. In: UpToDate, Eichler AF (ed), Waltham, MA. Accessed July 13, 2023.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes
- February 13, 2024: Removed criterion pertaining to patient or prescribing provider's office is located in Rhode Island (effective 5/1/2024).
- November 12, 2024: Added coverage criteria for Wakix's supplemental indication in treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy. Administrative update within the criteria to clarify the limitation statement that established clinical response excludes the use of samples (effective 1/1/2025).
- May 13, 2025: Removed Epworth Sleepiness Scale (ESS) and Maintenance of Wakefulness Test (MWT) from reauthorization criteria for Sunosi and Wakix (effective 6/1/2025).
- May 12, 2026: Expanded age requirement of Wakix for the treatment of cataplexy in pediatric patients to at least 6 years of age with narcolepsy based on expanded indication. Administrative update to remove CareLink from Medical Necessity Guideline template (effective 6/1/2026).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population

of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.