Pharmacy Medical Necessity Guidelines: Sunosi (solriamfetol) and Wakix (pitolisant)

Effective: January 18, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink[SM] – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

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 receptor antagonist/inverse agonist indicated for the treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy. Wakix should be administered once daily upon awakening. The recommended dosage range for Wakix is 17.8 mg to 35.6 mg daily. Hepatic and renal impairment should be taken into account when dosing Wakix.

COVERAGE GUIDELINES

Sunosi (solriamfetol)

The plan may authorize coverage of Sunosi for Members when all following criteria are met:

1. Member has a documented diagnosis of excessive daytime sleepiness associated with one of the following medical conditions:
   i. Narcolepsy
   ii. Obstructive sleep apnea/hypopnea syndrome

AND

2. **For treatment of excessive daytime sleepiness associated with obstructive sleep apnea,** there is documentation that the underlying airway obstruction is being treated (e.g., continuous positive airway pressure (CPAP)) concurrently

AND

3. The prescriber is a neurologist or sleep specialist, or a specialist consult is provided

AND

4. There is evidence of inadequate response, adverse reaction, or contraindication to modafinil and armodafinil

OR

The Member is new to Tufts Health Plan and has been stable on Sunosi for at least 2 months prior to enrollment

Wakix (pitolisant)

The plan may authorize coverage of Wakix for Members when all of the following criteria are met:

1. The Member has a diagnosis of excessive daytime sleepiness or cataplexy associated with narcolepsy

AND

2. The prescriber is a neurologist or sleep specialist, or a specialist consult is provided

AND

3. **For diagnosis of excessive daytime sleepiness associated with narcolepsy:** There is evidence of inadequate response, adverse reaction, or contraindication to all three of the following: modafinil, armodafinil, and Sunosi (solriamfetol)

OR

The Member is new to Tufts Health Plan and has been stable on Wakix for at least 2 months prior to enrollment

AND

4. **For diagnosis of cataplexy associated with narcolepsy:** The Member has had an inadequate response or intolerance to two, or contraindication to all, of the following: tricyclic antidepressant (TCA), atomoxetine, a selective serotonin reuptake inhibitor (SSRI), venlafaxine.

OR

The Member is new to Tufts Health Plan and has been stable on Wakix for at least 2 months prior to enrollment

Renewal Authorization for Sunosi (solriamfetol) and Wakix (pitolisant)

1. Documentation of a positive clinical response to therapy

AND

2. **Sunosi only:** For treatment of excessive daytime sleepiness associated with obstructive sleep apnea, there is documentation that the member is compliant with treatment(s) for the underlying airway obstruction (i.e. continuous positive airway pressure (CPAP))

LIMITATIONS

1. Sunosi and Wakix will not be authorized for non-medical conditions such as, but not limited to the following:
   - Shift work sleep disorder
   - Generalized fatigue
   - Travel (jet lag)
   - Sleep-deprivation (i.e., military or academic use)
2. The following quantity limitations apply to coverage. Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Quantity Limitations and submit a formulary exception request for those Members requiring higher quantities.

Sunosi (solriamfetol)	30 tablets per 30 days
Wakix (pitolisant)	60 tablets per 30 days

3. Duration of approval for treatment with Sunosi and Wakix is limited to 12 months

CODES

None

REFERENCES

1. Doghramji P, Lieberman J, Gordon M. Stay awake! Understanding, diagnosing, and successfully managing Narcolepsy. *J Fam Pract.* 2007;56(11):S19.
2. Harsh JR, Hayduk R, Rosenberg R, et al. The efficacy and safety of armodafinil as treatment for adults with excessive sleepiness associated with narcolepsy. *Curr Med Res Opin*. 2006;22(4): 761-74.
3. McNicholas WT. Diagnosis of Obstructive Sleep Apnea on Adults. *Proc Am Thorac Soc*. 2008; 5:154-60.
4. Morgenthaler TI, Kapur VK, Brown TM. Standards of practice committee of the AASM. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. *Sleep*. 2007; 30(12):1705-11.
5. Morgenthaler TI, Kapen S, Lee-Chiong T et al. Practice parameters for the medical therapy of obstructive sleep apnea. *Sleep*. 2006;29(8):1031-35.
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7. Roth T, Rippon GA, Arora S. Armodafinil improves wakefulness and long-term episodic memory in nCPAP-adherent patients with excessive sleepiness associated with obstructive sleep apnea. *Sleep Breath*. 2008;12(1):53-62.
8. Thorpy MJ, Shapiro C, Mayer G et al. A randomized study of solriamfetol for excessive sleepiness in narcolepsy. *Ann Neurol.* 2019; 85:359-70.

9. Sunosi (solriamfetol) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.
10. Wakix (pitolisant) [prescribing information]. Plymouth Meeting, PA: Harmony Biosciences; October 2020.

APPROVAL HISTORY

November 12, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. January 14, 2020: Added Wakix to the Medical Necessity Guideline. Updated title of MNG from "Sunosi" to "Sunosi and Wakix."
2. January 12, 2021: Effective 1/18/2021, updated criteria for Wakix to include diagnosis of cataplexy associated with narcolepsy.

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.