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

Effective: January 20, 2020

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<th>Prior Authorization Required</th>
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<th>Type of Review – Care Management</th>
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<tr>
<td>Not Covered</td>
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<td>Type of Review – Clinical Review</td>
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<tr>
<th>Pharmacy (RX) or Medical (MED) Benefit</th>
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<td>RX</td>
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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<sup>SM</sup> – 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 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 with 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:
   - Narcolepsy
   - 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 associated with narcolepsy

   AND

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

   AND

3. 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

**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**

- 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)

- 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.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity Limitation</th>
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<tr>
<td>Sunosi (solriamfetol)</td>
<td>30 tablets per 30 days</td>
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<tr>
<td>Wakix (pitolisant)</td>
<td>60 tablets per 30 days</td>
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- Duration of approval for treatment with Sunosi and Wakix is limited to 12 months

**CODES**

None

**REFERENCES**


11. **APPROVAL HISTORY**

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

Subsequent endorsement date(s) and changes made:


**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.