Pharmacy Medical Necessity Guidelines: Drugs for Treatment of Sleep Disorders

Effective: July 20, 2020

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℠ – 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

Armodafinil and modafinil are oral wakefulness-promoting medications, Food and Drug Administration-approved to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder. The precise mechanism of action is not fully known, but the resultant stimulation is similar in effect to amphetamine and methylphenidate, yet the pharmacological profile is not identical to these products.

Hetlioz (tasimelteon) is a melatonin receptor agonist to treat non-24 hour sleep-wake disorder in totally blind individuals.

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) in adult patients with narcolepsy.

COVERAGE GUIDELINES

Generic armodafinil and modafinil

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

1. Members have documented diagnosis of excessive daytime sleepiness associated with one of the following medical conditions:
   i. Narcolepsy
   ii. Depression
   iii. Chronic fatigue syndrome
   iv. Multiple sclerosis
   v. Organic brain disorder
   vi. Obstructive sleep apnea/hypopnea syndrome
   vii. Parkinson's disease
   viii. Idiopathic hypersomnia

Hetlioz (tasimelteon)
The plan may authorize coverage of Hetlioz (tasimelteon) for Members when **all** of the following criteria are met:

1. Documentation the Member is totally blind

AND

2. Documented diagnosis of Non-24 sleep-wake disorder by a sleep specialist

AND

3. The Member has had an insufficient response or intolerance to at least two (2) generic medications for sleep

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

1. Members have 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 (i.e. continuous positive airway pressure (CPAP)) concurrently

AND

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

AND

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

OR

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

Renewal Authorization for Sunosi (solriamfetol)

1. Documentation of a positive clinical response to therapy

AND

2. 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])

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

1. The member is 18 years of age or older

AND

2. The member has a documented diagnosis of excessive daytime sleepiness associated with narcolepsy

AND

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

AND

4. One of the following:
   a. There is evidence of inadequate response, adverse reaction, or contraindication to modafinil and armodafinil and Sunosi (solriamfetol)

   OR

   b. 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 Wakix (pitolisant)

1. Documentation of a positive clinical response to therapy

LIMITATIONS

1. Brand-name Provigil (modafinil) and Nuvigil (armodafinil) are not covered for all Commercial and Direct formularies. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.
2. Drugs for treatment of sleep disorders 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)

3. The plan will not cover Hetlioz for diagnosis of insomnia.
4. 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.

Hetlioz (tasimelteon) capsules	30 capsules per 30 days
Nuvigil (armodafinil)	90 tablets per 90 days
Provigil (modafinil)	180 tablets per 90 days
Sunosi (solriamfetol)	30 tablets per 30 days
Wakix (pitolisant)	60 tablets per 30 days

5. Initial authorization of Hetlioz (tasimelteon) will be for a period of four (4) months. Authorization over the initial four (4) months will require confirmation of continued efficacy and will be approved for life of plan.
6. Duration of approval for treatment with Sunosi is limited to 12 months
7. Duration of approval for treatment with Wakix is limited to 12 months
8. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

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. Hetlioz (tasimelteon) [prescribing information]. District of Columbia, U.S.: Vanda Pharmceuticals; Dec 2014.
4. McNicholas WT. Diagnosis of Obstructive Sleep Apnea on Adults. *Proc Am Thorac Soc*. 2008; 5:154-60.
5. 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.
6. 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.
7. Morgenthaler TI, Lee-Chiong T, Alessi C, et al. Practice parameters for the clinical evaluation and treatment of Circadian rhythm sleep disorders. *Sleep*. 2007;30(11):14445-59.
8. Nuvigil (armodafinil) [package insert]. Frazer, PA: Cephalon, Inc.; November 2018.
9. Pack, A, Black J, Schwartz J. Modafinil as adjunct therapy for the daytime sleepiness in obstructive sleep apnea. *Am J Respir Crit Care Med*. 2001;164:1675-81.
10. Provigil (modafinil) [package insert]. Frazer, PA: Cephalon, Inc.; November 2018.
11. 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.
12. Sunosi prescribing information. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; 2019 March.
13. Thorpy MJ, Shapiro C, Mayer G et al. A randomized study of solriamfetol for excessive sleepiness in narcolepsy. *Ann Neurol.* 2019; 85:359-70.
14. Wakix prescribing information. Plymouth Meeting, PA: Harmony Biosciences; 2019 August.

APPROVAL HISTORY

April 2000: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- February 8, 2005: Add to criteria #2 the diagnoses of "Parkinson's Disease," "Attention Deficit Disorder" and "Chronic Fatigue Syndrome." Change criteria #3 from "the requesting physician has documented that the Member has had a treatment failure of or is unable to tolerate **one** or more formulary alternative medications* (see attachment)" to "the Member has had a treatment

failure, inability to tolerate or other medical contraindication to one or more formulary alternative medications* (see attachment)."

- February 14, 2006: No changes
- January 9, 2007: No changes
- January 15, 2008: No changes
- November 11, 2008: Added automated step therapy coverage criteria to medical necessity guidelines. Added note that The plan does not consider generalized anxiety disorder (GAD) as a contraindication for treatment with a stimulant formulary alternative. Removed "Attention Deficit Disorder (ADD)" and "Attention Deficit Hyperactivity Disorder (ADHD)" from criteria #2.
- November 10, 2009: Added Nuvigil (armodafinil) to Pharmacy Medical Necessity Guidelines. Added dispensing limitations for Nuvigil (armodafinil) and Provigil (modafinil). Effective 01/01/2010, Tufts Medicare Preferred formularies will be included in the automated step therapy program (previously non-automated prior authorization).
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- November 9, 2010: Removed Concerta (methyphenidate ext-rel) from the list of formulary alternatives. Removed "Dispensing" from, "The following quantity limitations apply to coverage. Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Dispensing Limitations and submit a formulary exception request for those Members requiring higher quantities. Replaced with "Quantity".
- September 13, 2011: For effective date October 1, 2011: removed Provigil from Step Therapy criteria; as it is no longer covered on the Commercial Formularies.
- September 13, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
- May 8, 2012: Added modafinil to Step-2 of the Medical Necessity guidelines
- June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2.
- August 14, 2012: Removed non-covered brand product Provigil from step therapy grid and added this product to the limitations section. Added note that non-covered Provigil may qualify as a prerequisite for Step-2 medications. Added use of samples or vouchers/coupons for brand name medications limitation.
- June 11, 2013: No changes
- October 8, 2013: Administrative change: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
- April 1, 2014: Administrative update: Removed language pertaining to the Generic Focused Formulary and added EHB MA/RI Formulary.
- June 10, 2014: No changes
- June 9, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct
- May 10, 2016: No changes
- July 12, 2016: Added armodafinil to Step-2 for all Commercial Formularies. Moved Nuvigil to not covered for MA/RI/NH EHB Formularies.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- July 11, 2017: Updated Medical Necessity Guideline to note Nuvigil is not covered for all Commercial formularies.
- November 14, 2017: Reversed the order of criteria in step 2, to ask for treatment failure to one or more Step-1 formulary alternative medications prior to asking for an appropriate diagnosis. Also, listed the age restriction and PA requirements for step 1 medications.
- December 11, 2018: Administrative update to the template.
- May 7, 2019: Removed automated STPA and the requirement to step through a trial with amphetamine salts or methylphenidate.
- June 11, 2019: Added idiopathic hypersomnia to the list of approvable indications.
- November 12, 2019: Changed the name of the MNG to Drugs for Treatment of Sleep Disorders. Added Sunosi criteria and QL to the MNG.
- January 14, 2020: Added Wakix criteria and QL to the MNG and the limitation that samples do not qualify as an established clinical response for prior authorization.
- April 14, 2020: Effective April 14, 2020, Hetlioz criteria added to MNG. Hetlioz Medical Necessity Guideline retired (ID: 2210454). No changes to existing criteria.

- July 14, 2020: Updated sample limitation to the following: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

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.