UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Sunosi

Program	Prior Authorization
Medication	Sunosi (solriamfetol)
Markets in Scope	Arizona, Hawaii, Nevada, New Jersey, New York, New York EPP, Rhode Island, Pennsylvania-CHIP, California, South Carolina
Issue Date	7/2019
Pharmacy and Therapeutics Approval Date	5/2020
Effective Date	7/2020

1. Background:

Sunosi is a dopamine and norepinephrine reuptake inhibitor (DNRI) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).[1]

Limitations 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.

2. Coverage Criteria:

A. Narcolepsy

1. Initial Authorization

a. Sunosi will be approved based on **all** of the following criteria:

(1) Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy with **both** of the following:

(a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

(b) A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

-AND-

(2) Physician attestation to the following:

(a) Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders).

–AND–

(3) History of failure, contraindication, or intolerance to **both** of the following:

i. **One** of the following:

1. Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
2. Methylphenidate based stimulant

–AND–

ii. armodafinil

-AND-

(4) Prescribed by **one** of the following:

(a) Neurologist
(b) Psychiatrist
(c) Sleep Medicine Specialist

Authorization will be issued for 12 months.

2. Reauthorization

a. Sunosi will be approved for continuation of therapy based on the following criterion:

(1) Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

Authorization will be issued for 12 months.

B. Obstructive Sleep Apnea

1. Initial Authorization

a. Sunosi will be approved based on **all** of the following criteria:

(1) Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of obstructive sleep apnea with **one** of the following:

(a) Fifteen or more obstructive respiratory events per hour of sleep confirmed by a sleep study

–OR–

(b) **Both** of the following:

1. Five or more obstructive respiratory events per hour of sleep confirmed by a sleep study

–AND–

2. One or more of the following sign/symptoms are present:

(a) Daytime sleepiness
(b) Nonrestorative sleep
(c) Fatigue

(d) Insomnia
(e) Waking up with breath holding, gasping, or choking
(f) Habitual snoring noted by bed partner or other observer
(g) Observed apnea

–AND–

(2) **Both** of the following:

(a) Standard treatments for the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

–AND–

(b) Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

–AND–

(3) History of failure, contraindication, or intolerance to armodafinil

-AND-

(4) Prescribed by **one** of the following:

(a) Neurologist
(b) Psychiatrist
(c) Sleep Medicine Specialist

Authorization will be issued for 12 months.

2. Reauthorization

a. **Sunosi** will be approved for continuation of therapy based on **both** the following criteria:

(1) Reduction in symptoms of excessive daytime sleepiness associated with Sunosi therapy

–AND–

(2) Patient continues to be fully compliant with ongoing treatment(s) for the

underlying airway obstruction (e.g. CPAP, BiPAP)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Sunosi [package insert]. Jazz Pharmaceuticals, Inc. Palo Alto, CA. June 2019.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders: Diagnostic and Coding Manual. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
3. Morgenthaler TI1, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007 Dec;30(12):1705-11.
4. Wise MS1, Arand DL, Auger RR, et al. Treatment of narcolepsy and other hypersomnias of central origin. Sleep. 2007 Dec;30(12):1712-27.

Program	Prior Authorization
Change Control	
Date	Change
7/2019	New program
8/2019	Added step through amphetamine or methylphenidate-based stimulant to match Xyrem program.
5/2020	Added requirement for submission of documentation of sleep study with specific sleep study requirements for narcolepsy. Added requirement for prescriber specialty. Changed initial authorization duration to 12 months.