

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	NA	X	X	NA

Sunosi (solriamfetol)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

**Maryland Medicaid – see State Specific Mandates below*

Medications	Quantity Limit
Sunosi (solriamfetol)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Sunosi (solriamfetol) may be approved if the following criteria are met:

- I. Individual 18 years of age or older; **AND**
- II. Individual is using to treat excessive daytime sleepiness associated with one of the following diagnoses:
 - A. Narcolepsy type 1 confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least **ONE** of the following (ICSD-3):
 1. Clear cataplexy (defined as “more than one episode of generally brief [<2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness”); **AND**
 2. Multiple Sleep Latency Test (MSLT) showing **ONE** of the following:
 - a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs); **OR**
 - b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);
 - OR**
 3. Cerebrospinal fluid hypocretin-1 deficiency (less than <100 pg/mL or less than one-third of the normative values with the same standardized assay);
- OR**
- B. Narcolepsy type 2 confirmed by the following (ICSD-3):
 1. Multiple sleep latency test (MSLT) with **ONE** of the following:
 - a. MSLT of less than 8 minutes and evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
 - b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);

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AND

2. The absence of cataplexy; **AND**
3. Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam, and PSG;

OR

- C. Obstructive Sleep Apnea-Hypopnea Syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing **ONE** of the following (AASM 2017, ICSD-3):
 1. Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep); **OR**
 2. Greater than 5 obstructive events per hour of sleep and individual reports any of the following:
 - a. Unintentional sleep episodes during wakefulness; **OR**
 - b. Daytime sleepiness; **OR**
 - c. Unrefreshing sleep; **OR**
 - d. Fatigue; **OR**
 - e. Insomnia; **OR**
 - f. Waking up holding breath, gasping or choking; **OR**
 - g. Bed partner describing loud snoring, breathing interruptions or both; **OR**
 - h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus;

AND

3. Individual has an Epworth Sleepiness Scale score greater than or equal to 10, despite treatment with continuous positive airway pressure (CPAP); **AND**
4. Modalities for treating the underlying airway obstruction will be continued during treatment;

AND

- III. Individual has had a trial of and inadequate response or intolerance to one of the following medications:
 - A. Modafinil; **OR**
 - B. Armodafinil.

Requests for Sunosi (solriamfetol) may **not** be approved for the following:

- I. Individual is currently using a monoamine oxidase inhibitor (MAOI); **OR**
- II. Individual has used an MAOI within the preceding 14 days; **OR**

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III. Individual has end stage renal disease (ESRD) (eGFR < 15 mL/min/1.73²).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Maryland		Maryland behavioral health is state carve out.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 8, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults: Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2009; 5(3):263-276. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173/pdf/jcsm.5.3.263.pdf>. Accessed March 8, 2019.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
6. Wise MS, Arand DL, Auger RR, Brooks SN, Watson NF; American Academy of Sleep Medicine. Treatment of Narcolepsy and other Hypersomnias of Central Origin. *Sleep*. 2007 Dec 1;30(12):1712-27. Available from: http://www.aasmnet.org/Resources/PracticeParameters/Review_Narcolepsy.pdf. Accessed March 8, 2019.

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