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

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);

Market Applicability							
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Applicable	X	X	X	NA	X	X	NA

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 (medication samples/coupons/discount cards are excluded from consideration as 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**
III. Individual has end stage renal disease (ESRD) (eGFR < 15 mL/min/1.73^2).

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

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply