Sunosi

I. Generic Name:
- a. Solriamfetol

II. Brand Name:
- a. Sunosi

III. Medication Class:
- a. Dopamine and norepinephrine reuptake inhibitor

IV. FDA Approved Uses:
- a. Narcolepsy or obstructive sleep apnea: To improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA)

V. Application of Criteria:
- a. The following criteria apply to Illinois Medicaid, Michigan Medicaid, and Meridian Choice (HIX)

VI. Criteria for Use:
- a. Narcolepsy:
    - A. Member must be 18 years of age or older
    - B. Prescribed by a physician specializing in sleep medicine
    - C. Patient must be clinically diagnosed with narcolepsy and have excessive daytime sleepiness that is substantial enough to warrant treatment
    - D. Clinical documentation of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months
    - E. Exclusion of alternative causes of chronic daytime sleepiness (e.g. insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, idiopathic hypersomnia, effects of sedating medications)
    - F. Documentation of compliance to non-pharmacologic interventions (e.g. napping/sleep hygiene, avoidance of medications that can worsen daytime sleepiness [benzodiazepines, opiates, antipsychotics, alcohol, theophylline, excessive caffeine])
    - G. Current chart notes with plan of care recommending treatment with Sunosi
    - H. Documentation of adequate trial and failure and compliance to at least 3 months of treatment with each of the following:

i. Methylphenidate
ii. Dextroamphetamine/amphetamine
iii. Modafinil

b. Obstructive sleep apnea
   A. Member must be 18 years of age or older
   B. Prescribed by a physician specializing in sleep medicine
   C. Patient must be clinically diagnosed with OSA and have excessive daytime sleepiness that is substantial enough to warrant treatment
   D. Current chart notes with plan of care recommending treatment with Sunosi
   E. Documentation of adequate, proper functioning and compliance with positive airway pressure (PAP) therapy
   F. Exclusion of alternative causes of chronic daytime sleepiness (e.g. insufficient sleep, effects of sedating medications, comorbid medical and psychiatric disorders such as depression)
   G. Repeat polysomnography (while wearing PAP device) to assess if OSA therapy is adequate
   H. Epworth Sleepiness Scale score (ESS) of 12 or higher
   I. Documentation of adequate trial and failure and compliance to at least 3 months of treatment with modafinil

VII. Required Medical Information:

a. Proper diagnosis and documentation of an FDA approved indication
b. Current progress notes detailing the diagnosis with plan of care
c. Documentation of dose, date ranges of therapy, and clinical outcomes for all medications previously tried and failed
d. Complete chart notes documenting disease history
e. Charts showing compliance to previous therapy and office visits
f. Narcolepsy:
   A. Polysomnography (PSG) consistent with narcolepsy ruling out other sleep disorders
   B. Multiple sleep latency test (MSLT) documenting mean sleep latency of $\leq$ 8 minutes and two or more sleep onset REM periods (SOREMPs)
   C. Baseline Epworth Sleepiness Scale (ESS) score
   D. Documentation of CSF hypocretin concentration measured by immunoreactivity of either > 110 pg/mL or >1/3 of mean values obtained in normal subjects with the same standardized assay (Not required if lab work has not been performed)
g. Obstructive sleep apnea:
   A. Initial polysomnography (PSG) diagnostic of OSA

B. Repeat polysomnography (PSG) while wearing PAP device
C. Baseline Epworth Sleepiness Scale (ESS) score

VIII. Contraindications:

a. Hypersensitivity to solriamfetol or any component of the formulation
b. Concomitant use with or within 14 days of an MAOI

IX. Not Approved If:

a. Narcolepsy: Request is for Sunosi as combination therapy used concurrently with either Wakix or Xyrem
b. OSA: Request is for Sunosi as combination therapy used concurrently with either modafinil or Nuvigil
c. Patient shows non-compliance with previous treatment based on progress notes and/or pharmacy claims/fill history for required step therapies
d. Patient shows any contraindications to the use of Sunosi as outlined in the FDA approved prescribing information
e. Request is for a non-FDA approved indication or dose

X. Length of Authorization:

a. Initial: 3 months
b. Continuation: up to 6 months

XI. Dosing:

a. Narcolepsy:
    A. Initial dosage: 75 mg once daily
    B. Dosage adjustment: May increase based on response and tolerability at an interval of ≥3 days to the maximum dose of 150 mg/day
b. Obstructive sleep apnea:
    A. Initial dosage: 37.5 mg once daily
    B. Dosage adjustment: Based on response and tolerability, may double the dose at intervals of ≥3 days up to the maximum dose of 150 mg/day

XII. Criteria for Continuation of Therapy:

a. Initial therapy was tolerated
b. Demonstrated improvement in disease (improvement in the Epworth Sleepiness Scale score)
c. Patient must be compliant with taking the medication as prescribed
d. OSA: Patient must be compliant with positive airway pressure (PAP) therapy

e. Patient must not be experiencing any severe adverse reaction while taking the medication
f. Office visit every 3-6 months with verified compliance and improvement or stability on drug

XII. Criteria for Discontinuation of Therapy:

a. Patient is non-compliant with pharmacologic or non-pharmacologic therapy (e.g. positive airway pressure [PAP] therapy)
b. No demonstrable clinically significant improvement after initiation and stabilization of drug therapy
c. Patient is non-responsive to FDA-approved usual maximum dosing

XIII. References:

1. Solriamfetol: Facts and Comparisons. Wolters Kluwer Health. April 2020
2. Sunosi (solriamfetol) Prescribing Information. Palo Alto, CA; Jazz Pharmaceuticals Inc.: June 2019.
3. Baladi MG, Forster MJ, Gatch MB, et al. Characterization of the neurochemical and behavioral effects of solriamfetol (JZP-110), a selective dopamine and norepinephrine reuptake inhibitor. J Pharmacol Exp Ther. 2018; 366(2):367-376.
4. Gasa M, Tamisier R, Launois SH, et al. Residual sleepiness in sleep apnea patients treated by continuous positive airway pressure. J Sleep Res 2013; 22:389.
5. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep 2007; 30:1705.
6. Scammell TE. The neurobiology, diagnosis, and treatment of narcolepsy. Ann Neurol 2003; 53:154.
7. Schweitzer PK, Rosenberg R, Zammit GK, et al. Solriamfetol for Excessive Sleepiness in Obstructive Sleep Apnea (TONES 3). A Randomized Controlled Trial. Am J Respir Crit Care Med 2019; 199:1421.
8. Strollo PJ Jr, Hedner J, Collop N, et al. Solriamfetol for the Treatment of Excessive Sleepiness in OSA: A Placebo-Controlled Randomized Withdrawal Study. Chest 2019; 155:364.
9. Thorpy MJ, Shapiro C, Mayer G, et al. A randomized study of solriamfetol for excessive sleepiness in narcolepsy. Ann Neurol 2019; 85:359.

meridianRx

P.260 Approval Criteria

Sunosi

Approved by: _____ Date: _____
CMO

Initial Approval:	
Revised:	
Annual Review:	
Next Review Date:	