SOLRIAMFETOL

Generic	Brand	HICL	GCN	Exception/Other
SOLRIAMFETOL	SUNOSI	45666		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy **AND** physician attestation that narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient had a trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil

   If yes, **approve for 6 months by HICL with a quantity limit of #1 tablet per day.**
   APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) **AND** physician attestation that OSA is confirmed by **ONE** of the following criteria?
   - Polysomnography
   - Home sleep apnea testing devices
   - Hospital-based bedside monitoring

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
   - The patient had a trial of or contraindication to modafinil or armodafinil
   - Physician attestation that the patient is on ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and has been counseled on weight-loss intervention (if BMI > 30)

   If yes, **approve for 6 months by HICL with a quantity limit of #1 tablet per day.**
   APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **SOLRIAMFETOL (Sunosi)** requires a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA). In addition, the following criteria must be met:
   For the diagnosis of excessive daytime sleepiness (EDS) with narcolepsy, approval requires:
   - Physician attestation that narcolepsy is confirmed by **ONE** of the following:
     - The patient has a Multiple Sleep Latency Test (MSLT) showing a both mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
     - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
     - The patient has low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay
   - Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10

   Initial denial text continued on the next page

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INITIAL CRITERIA (CONTINUED)

- Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
- The patient had a trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil

For the diagnosis of excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval requires:

- Physician attestation that OSA is confirmed by polysomnography, home sleep apnea testing devices, or hospital-based bedside monitoring
- Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
- The patient had a trial of or contraindication to modafinil or armodafinil
- Physician attestation that the patient is on ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and have been counseled on weight-loss intervention (if BMI > 30)

RENEWAL CRITERIA

2. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA) **AND** meet the following criterion?
   - Physician attestation that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline

   If yes, **approve for 12 months by HICL with a quantity limit of #30 per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **SOLRIAMFETOL (Sunosi)** requires a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA). In addition, the following must be met:
   - Physician attestation of sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunosi.

REFERENCES

- Sunosi [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/19
Created: 07/19
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P&T Approval: 10/19