I. Medication Description

Sedative hypnotics are indicated for the treatment of insomnia. Some manufacturer guidelines recommend 7 to 10 days of use; re-evaluate patient if therapy is to be taken for more than 2 to 3 weeks. In March 2007 the FDA ordered a class labeling change to all sedative hypnotics requiring the following to be added to the warning section: The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Sedative hypnotics are generally over-prescribed and given for longer durations than recommended for a healthy sleep-hygiene regimen. Short-acting, non-benzodiazepines are often “over-promoted” as safer and less addicting than benzodiazepine hypnotics, but these advantages have never been conclusively proven.

II. Position Statement

- **Plan-preferred medications**: zaleplon, zolpidem, zolpidem CR
- **Non-preferred medications**: Ambien, Ambien CR, Belsomra, Edluar, eszopiclone, Lunesta, Intermezzo, Rozerem, Silenor, Sonata, zolpidem SL tablets, Zolpimist
- Coverage is provided immediately for up to 12 tablets/capsules per 30 days of a plan-preferred medication.
- Coverage for a non-preferred medication is determined through a prior authorization process for every claim.
- Quantity limits apply to all medications.

III. Policy

Coverage of non-preferred medications is provided when the following criteria are met:
- Coverage of Edluar or Zolpimist is provided for members with a documented swallowing disorder who are unable to utilize regular dosage forms including capsules or tablets- whole or crushed OR
- Coverage of Intermezzo or zolpidem SL is provided for members with middle-of-the-night awakening that is followed by difficulty returning to sleep when a trial with plan-preferred medication zaleplon has been attempted and has not adequately treated the condition OR
- Coverage of Silenor or Rozerem is provided for members who either have a documented history of substance abuse or who have first experienced treatment failure (or have been intolerant to treatment with) at least one plan-preferred medication OR
- Coverage of Ambien, Ambien CR, Belsomra, eszopiclone, Lunesta, or Sonata is provided for members who have first experienced treatment failure (or have been intolerant to treatment with) at least one plan-preferred medication OR
- The following step criteria are met:
  - When requesting coverage of a brand medication for which an A/B rated generic is available, there is sufficient evidence that the use of the A/B rated generic equivalent has shown inadequate results **AND**
At least one of the following must be met:

- The plan-preferred medications are contraindicated or will likely cause an adverse reaction by or physical or mental harm to the member.
- The plan-preferred medications are expected to be ineffective based on the known clinical history and conditions of the member and the member’s prescription drug regimen.
- The member has tried the plan-preferred medications or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
- The member is stable on the medication selected by their healthcare professional for the medical condition under consideration (where “stable” is defined as receiving the medication for an adequate period of time, have achieved optimal response, and continued favorable outcomes are expected UNLESS the medication was initially selected due to the availability of a drug sample or a coupon card).
- The plan-preferred medication is not in the best interest of the member because it will likely cause a significant barrier to the member’s adherence or to compliance with the member’s plan of care, will likely worsen a comorbid condition of the member, or will likely decrease the member’s ability to achieve or maintain reasonable functional ability in performing daily activities.

IV. Quantity Limitations

- Coverage of Rozerem and Silenor is provided for 30 tablets per 30 days.
- Coverage of Zolpidem is provided for 1 bottle per 30 days
- Coverage of all other medications is provided for 12 tablets/capsules/doses per 30 days.  
  - Coverage for quantities greater than 12 tablets/capsules per 30 days can be approved with a documented diagnosis of chronic insomnia, where:
    - The request for increased quantity comes from a sleep specialist, pulmonologist, psychiatrist, neurologist or other certified sleep specialist (Certified International Sleep Specialist or Diplomat of the American Board of Sleep Medicine) OR
    - The following are documented:
      - The member has had an adequate trial and experienced treatment failure with as needed usage (requiring nightly or greater than 12 doses per month) AND
      - The member has a significant underlying cause of insomnia that is otherwise being adequately treated.
  
- Maximum approved quantities of Sonata (zaleplon): 60 capsules per 30 days
- Maximum approved quantities of all others listed above: 30 tablets/doses per 30 days

V. Coverage Duration

- Coverage of Rozerem and Silenor is provided indefinitely for the life of this policy.
- For all other medications, coverage is provided for 12 months and may be renewed.
VI. Coverage Renewal Criteria

Coverage of a non-preferred medication can be renewed in the following situations:
- The member is benefitting from therapy AND
- There are no unacceptable toxicities attributed to use of the medication

Coverage of nightly therapy can be renewed in the following situations:
- The member is benefitting from therapy AND
- There are no unacceptable toxicities attributed to the use of the medication AND
- There is still a reason nightly therapy is warranted

VII. Billing/Coding Information

- Sonata® (zaleplon): 5mg and 10mg capsules
- Ambien® (zolpidem): 5mg and 10mg tablets
- Ambien® CR (zolpidem CR): 6.25 and 12.5mg tablets
- Lunesta®/eszopiclone: 1mg, 2mg, and 3mg tablets
- Rozerem®: 8mg tablets
- Silenor®: 3mg and 6mg tablets
- Edluar®: 5mg and 10mg sublingual tablets
- ZolpiMist™: 5mg/actuation oral spray, one 7.7ml bottle contains 60 actuations
- Intermezzo®/zolpidem SL: 1.75mg and 3.5mg sublingual tablets
- Belsomra®: 5mg, 10mg, 15mg, and 20mg tablets

VIII. Summary of Policy Changes

- 12/2010: Silenor added to policy
- 1/1/12: no changes
- 3/2012: Intermezzo added to policy, approval duration extended for Rozerem, updated to include reference to Medicaid/Family Health Plus population
- 12/15/12:
  - Certified sleep specialists added to accepted prescribers for quantity overrides
  - Criteria clarified as: allowing increased quantities for significant underlying medical conditions otherwise being treated
- 2/2013: clarification that preferred medication portion of policy pertains to members aged 18 and older added
- 6/15/13: Multi-source brands added as targeted medications
- 12/15/13:
  - Criteria for Rozerem coverage updated
  - Silenor approvals increased to indefinite timeframe
- 4/21/14: eszopiclone added to policy
- 9/5/14: Belsomra added to policy
- 1/1/15: no policy changes
IX. References

7. Members of the National Heart Lung and Blood Institute Working Group on Insomnia, materials at www.NHLBI.NIH.GOV
guidelines.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.
The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.