MEDICATION POLICY

Generic Name: Non-Preferred Hypnotics

Therapeutic Class or Brand Name: Non-Preferred Hypnotics

Applicable Drugs (if Therapeutic Class)**:**

Belsomra® (suvorexant), Edluar® (zolpidem SL), Intermezzo® (zolpidem SL), Rozerem® (ramelteon), and ZolpiMist® (zolpidem oral spray).

Policy also applies to any other Non-Preferred Hypnotics not listed.

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 9/23/16

GPI Code: 6020408010, 6025006000, 6050007000

Prior Authorization Criteria (may be considered medically necessary when criteria I through VIII are met):

I. Documented diagnosis of insomnia.

II. Patient has difficulty initiating or maintaining sleep, or non-restorative sleep has occurred for at least one month.

III. Patient has specific measurable functional impairment due to insomnia.

IV. The sleep disturbance is not due to otherwise reversible conditions. Other reversible conditions may include, but are not limited to, another sleep disorder, mental disorder, or physiological effects of another substance.

V. Non-pharmacologic therapies have been inadequate in improving functional impairments. Examples of non-pharmacologic therapies include, but are not limited to, stimulus control therapy, sleep restriction therapy, relaxation therapy, or cognitive therapy.

VI. Patient has documented trials and failures of or contraindications to generic zolpidem AND at least one other generic medication used for sleep (i.e. doxepin, eszopiclone, triazolam, zaleplon, etc.).

VII. Patient must also have a documented inability to take any medications by mouth if request is for Edluar®, Intermezzo®, or ZolpiMist®.

VIII. Minimum age requirement: 18 years old.

Exclusion Criteria:

- Concomitant use of Belsomra® with strong inhibitors of CYP3A (i.e. ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, boceprevir, telaprevir, telithromycin and conivaptan).
- Concomitant use of Rozerem® with fluvoxamine.
- Concomitant, alternating, or repeated sequential use of Belsomra®, Edluar®, Intermezzo®, Rozerem®, or ZolpiMist® with other Hypnotics (i.e. eszopiclone, temazepam, zaleplon, zolpidem, etc.) exceeding 14 tablets per month is considered duplication of therapy and not medically necessary.
- Belsomra® is contraindicated in patients with narcolepsy.

Other Criteria:

- Doses exceeding the following are considered not medically necessary:
  - Belsomra®: 20mg per day.
  - Edluar®, ZolpiMist®: 10mg per day.
  - Intermezzo®: 1.75 mg per day for women or 3.5mg per day for men.
  - Rozerem®: 8mg per day.

Quantity/Days Supply Restrictions:

- Belsomra®, Edluar®, Intermezzo®, Rozerem®: Quantities up to 30 tablets per 30 days.
- ZolpiMist®: One spray bottler per 30 days.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** Up to 1 year. An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective.

Appendix:

N/A

References:

1. http://blue.regence.com/trgmedpol/drugs/dru350.pdf.
2. http://blue.regence.com/trgmedpol/drugs/dru182.pdf.

3. Medi-Span.
4. http://general.takedapharm.com/content/file.aspx?applicationCode=5237EE08-766E-492D-B0F7-01CDB6161181&fileTypeCode=ROZEREMPI&cacheRandomizer=d5d1ce68-7df1-43fa-831e-3cc3d0dc9023.
5. http://www.edluar.com/pdf/EDLUAR-PI.pdf.
6. http://app.purduepharma.com/xmlpublishing/pi.aspx?id=i.
7. http://myzolpimist.com/wp-content/uploads/2016/04/Zolpimist-PI-approved-final.pdf.
8. http://www.merck.com/product/usa/pi_circulars/b/belsomra/belsomra_pi.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
9/23/2016	1. **Updated** "http://edluar.com/EDLUAR-PI.pdf" **to** "http://www.edluar.com/pdf/EDLUAR-PI.pdf" **and** "http://ecrpharma.com/site/wp-content/uploads/2013/09/ZolpimistLabeling.pdf" **to** "http://myzolpimist.com/wp-content/uploads/2016/04/Zolpimist-PI-approved-final.pdf" **under References**.
3/11/2015	1. **Added** "Belsomra® (suvorexant)" **to Applicable Drugs**. 2. **Added** "6050007000" **to GPI Code**. 3. **Added** "Concomitant use of Belsomra® with strong inhibitors of CYP3A (i.e. ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, boceprevir, telaprevir, telithromycin and conivaptan)" **and** "Belsomra® is contraindicated in patients with narcolepsy" **under Exclusion Criteria**. 4. **Changed** "Concomitant, alternating, or repeated sequential use of Edluar®, Intermezzo®, Rozerem®, or ZolpiMist® with other Hypnotics (i.e. eszopiclone, temazepam, zaleplon, zolpidem, etc.) exceeding 14 tablets per month is considered duplication of therapy and not medically necessary" **to** "Concomitant, alternating, or repeated sequential use of Belsomra®, Edluar®, Intermezzo®, Rozerem®, or ZolpiMist® with other Hypnotics (i.e. eszopiclone, temazepam, zaleplon, zolpidem, etc.) exceeding 14 tablets per month is considered duplication of therapy and not medically necessary" **under Exclusion Criteria**. 5. **Changed** "Edluar®, ZolpiMist®: Doses exceeding 10 mg per day are considered not medically necessary; Intermezzo®: Doses exceeding 1.75 mg for women or 3.5 mg for men per day are considered not medically necessary; Rozerem®: Doses exceeding 8 mg per day are considered not medically necessary" **to** "Doses exceeding the following are considered not medically necessary: Belsomra®: 20mg per day; Edluar®, ZolpiMist®: 10mg per day; Intermezzo®: 1.75 mg per day for women or 3.5mg per day for men; Rozerem®: 8mg per day" **under Other Criteria**. 6. **Changed** "Edluar®, Intermezzo®, Rozerem®: Quantities up to 30 tablets per 30 days" **to** "Belsomra®, Edluar®, Intermezzo®, Rozerem®: Quantities up to 30 tablets per 30 days" **under Quantity/Days Supply Restrictions**. 7. **Added** "http://www.merck.com/product/usa/pi_circulars/b/belsomra/belsomra_pi.pdf" **under References**.
3/10/2015	1. **Changed Applicable Drugs from** "Lunesta® (eszopiclone) and Rozerem® (ramelteon)" **to** "Edluar® (zolpidem SL), Intermezzo® (zolpidem SL), Rozerem® (ramelteon), and ZolpiMist® (zolpidem oral spray)". 2. **Changed GPI Code from** "6020403500, 6025006000" **to** "6020408010, 6025006000". 3. **Changed** "Non-Preferred Hypnotics require documented trials and failures of or contraindications to generic zolpidem and at least one other generic medication used for sleep" **to** "Patient has documented trials and failures of or contraindications to generic zolpidem AND at least one other generic medication used for sleep (i.e. doxepin, eszopiclone, triazolam, zaleplon, etc.)" **under Prior Authorization Criteria**. 4. **Added** "Patient must also have a documented inability to take any medications by mouth if request is for Edluar®, Intermezzo®, or ZolpiMist®" **under Prior Authorization Criteria**. 5. **Added** "Concomitant use of Rozerem® with fluvoxamine" **to Exclusion Criteria**. 6. **Changed** "Concomitant, alternating, or repeated sequential use of Lunesta® or Rozerem® with other Hypnotics (i.e. temazepam, zaleplon, zolpidem, etc.) exceeding 14 tablets per month is considered duplication of therapy and not medically necessary" **to** "Concomitant, alternating, or repeated sequential use of Edluar®, Intermezzo®, Rozerem®, or ZolpiMist® with other Hypnotics (i.e. eszopiclone, temazepam, zaleplon, zolpidem, etc.) exceeding 14 tablets per month is considered duplication of therapy and not medically necessary" **under Exclusion Criteria**. 7. **Changed** "Lunesta®: Doses exceeding 3 mg per day are considered not medically necessary; Rozerem®: Doses exceeding 8 mg per day are considered not medically necessary" **to** "Edluar®, ZolpiMist®: Doses exceeding 10 mg per day are considered not medically necessary; Intermezzo®:

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Historical Tracking Of Changes Made To Policy	
	Doses exceeding 1.75 mg for women or 3.5 mg for men per day are considered not medically necessary; Rozerem®: Doses exceeding 8 mg per day are considered not medically necessary" **under Other Criteria**. 8. **Changed** "Quantities up to 30 tablets per 30 days" **to** "Edluar®, Intermezzo®, Rozerem®: Quantities up to 30 tablets per 30 days; ZolpiMist®: One spray bottler per 30 days" **under Quantity/Days Supply Restrictions**. 9. **Updated** "http://blue.regence.com/trgmedpol/drugs/dru114.pdf" **and** "http://blue.regence.com/trgmedpol/drugs/dru124.pdf" **to** "http://blue.regence.com/trgmedpol/drugs/dru350.pdf" **under References**. 10. **Added** "http://blue.regence.com/trgmedpol/drugs/dru182.pdf"**,** "http://edluar.com/EDLUAR-PI.pdf"**,** "http://app.purduepharma.com/xmlpublishing/pi.aspx?id=i"**, and** "http://ecrpharma.com/site/wp-content/uploads/2013/09/ZolpimistLabeling.pdf" **under References**. 11. **Removed** "http://www.lunesta.com/pdf/PostedApprovedLabelingText.pdf" **from References**.
1/23/2014	1. **Adapted policy to new format.** 2. **Added GPI Codes**. 3. **Added** "Documented diagnosis of insomnia" **to Prior Authorization Criteria**. 4. **Changed** "Non-Preferred Hypnotics require documented trials and failures of or contraindications to ALL preferred generic Hypnotics (temazepam, zaleplon, and zolpidem)" **to** "Non-Preferred Hypnotics require documented trials and failures of or contraindications to generic zolpidem and at least one other generic medication used for sleep" **under Prior Authorization Criteria**. 5. **Added** "Minimum age requirement: 18 years old" **to Prior Authorization Criteria**. 6. **Changed Quantity/Days Supply Restrictions from** "34 tablets per month" **to** "Quantities up to 30 tablets per 30 days". 7. **Updated references** to include Medi-Span and package inserts.