



Medication Audit Criteria and Guidelines

Non-benzodiazepine Sedative Hypnotics

- Eszopiclone (Lunesta)
- Zolpidem (Ambien)

PEFC Approved: August 2020

Indications

- Difficulties with sleep initiation (eszopiclone, zolpidem)
- Difficulties with sleep maintenance (eszopiclone)

Black Box Warning

Complex Sleep Behaviors (sleep-walking, sleep-driving, engaging in other activities while not fully awake)

Contraindications

Absolute

- Complex sleep behaviors after taking zolpidem or eszopiclone
- Known hypersensitivity to zolpidem or eszopiclone. Hypersensitivity reactions include anaphylaxis and angioedema.

Relative

- Pregnancy and Breastfeeding

Precautions

- Abnormal Thinking and Behavioral Changes
- CNS-Depressant Effects and Next-Day Impairment
- Complex Sleep Behaviors
- Need to Evaluate for Comorbid Diagnoses
- Precipitation of Hepatic Encephalopathy (zolpidem)
- Respiratory Depression
- Severe Anaphylactic and Anaphylactoid Reactions
- Timing of Drug Administration
- Use in Patients with Depression
- Withdrawal Effects

Adverse Reactions

Side Effects Which Require Medical Attention

- Ataxia
- Confusion or disorientation
- Falling or dizziness
- Rash
- Worsening agitation, disinhibition, or aggression

Pregnancy and Breastfeeding

- See relative contraindications
- Review product-specific labeling. Consider risks/benefits in reviewing medication-specific labeling

Drug Interactions of Major Significance

See: [Indiana Univ Drug Interaction Table](#)

Special Populations

Age-Specific Considerations

- Pediatrics/Adolescents
 - Safety and efficacy have not been established in children younger than 18 years
 - “Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version)” reviewed both eszopiclone and zolpidem but they were not included/recommended
- Geriatric - Included in Beers Criteria, avoid use as potentially inappropriate in older adults

Renal Impairment

- No dosage adjustment needed

Hepatic Impairment

- Mild to moderate hepatic impairment: eszopiclone – no dosage adjustment; maximum zolpidem dose 5 mg
- Severe hepatic impairment: maximum eszopiclone dose 2 mg; avoid zolpidem use

Hemodialysis

- No dosage adjustment needed

Patient Monitoring Parameters

- Pregnancy Test—Baseline and as clinically indicated

Dosing

- See HHSC Psychiatric Drug Formulary for dosage guidelines.
- Exceptions to maximum dosage must be justified as per medication rule.