Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy:
Doxepin (Silenor) and suvorexant (Belsomra) are approved when there is documentation of ALL of the following:
1. Diagnosis of insomnia; and
2. Inadequate response or inability to tolerate ramelteon (Rozerem); and
3. Inadequate response or inability to tolerate TWO of the following:
   a. Eszopiclone
   b. Zaleplon
   c. Zolpidem

Edluar 5mg, Zolpimist, Intermezzo 1.75mg are approved when documentation is provided of ALL of the following:

1. Diagnosis of insomnia; and
2. One of the following:
   a. Inadequate response or inability to tolerate TWO of the following:
      i. Eszopiclone
      ii. Zaleplon
      iii. Zolpidem
   b. Inability to swallow capsules/tablets (e.g., dysphagia, gastrointestinal [GI] tubes)

Any of the following high dose products (brand and generic): Zolpidem tartrate (Ambien) 10mg, Zolpidem tartrate ER (Ambien CR) 12.5mg, Zolpidem tartrate SL (Intermezzo) 3.5mg, Eszopiclone (Lunesta) 3mg and Edluar 10mg are approved when there is documentation of ALL of the following:

1. Diagnosis of insomnia; and
2. Patient has been counseled on practices associated with good sleep hygiene (e.g. avoiding stimulants such as caffeine, nicotine, alcohol close to bed time, etc.); and
3. Titration history (as recommended by dosing guidelines for individual product) demonstrating an appropriate trial of the lower dose of the requested product; and
4. Inadequate response to a two week trial of the lower dose
5. Inadequate response or inability to tolerate a generic equivalent (applies to BRANDS with generic equivalents only)

Tasimelteon (Hetlioz®) is approved when ALL of the following inclusion criteria are met:

1. Member is 18 years of age or older; and
2. Member is totally blind; and
3. Diagnosis of a circadian period greater than 24 hours by a sleep specialist; and
4. Inadequate response or inability to tolerate ramelteon (Rozerem)

**Black Box Warning:**

None

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


**Applicable Drugs:**

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tr>
<td>Ambien 10mg</td>
<td>zolpidem tartrate immediate release 10mg</td>
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<tr>
<td>Ambien CR 12.5mg</td>
<td>zolpidem tartrate extended release 12.5mg</td>
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<tr>
<td>Edluar 10mg</td>
<td>zolpidem sublingual tablets 10mg</td>
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<td>Silenor</td>
<td>doxepin</td>
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<tr>
<td>Zolpimist</td>
<td>zolpidem</td>
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<tr>
<td>Intermezzo 3.5mg</td>
<td>zolpidem 3.5mg</td>
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Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.
Cross References:

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<tr>
<td>P&amp;T Approval Date:</td>
<td>January 14, 2016</td>
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<tr>
<td>Policy Effective Date:</td>
<td>March 01, 2016</td>
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<td>Next Required Review Date:</td>
<td>October 08, 2016</td>
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