Clinical Policy: Lemborexant (Dayvigo)
Reference Number: CP.PMN.233
Effective Date: 06.01.20
Last Review Date: 05.20
Line of Business: Commercial, HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Lemborexant (Dayvigo™) is an orexin receptor antagonist.

FDA Approved Indication(s)
Dayvigo is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Dayvigo is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Insomnia (must meet all):
      1. Diagnosis of insomnia;
      2. Age ≥ 18 years;
      3. Failure of two preferred or formulary agents indicated for insomnia (see Appendix B for examples) at maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
      4. Dose does not exceed 10 mg (1 tablet) per day.
   Approval duration: 6 months

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy
   A. Insomnia (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 10 mg (1 tablet) per day.
   Approval duration: 12 months
B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
      **Approval duration: Duration of request or 12 months (whichever is less):** or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
   **Appendix A: Abbreviation/Acronym Key**
   FDA: Food and Drug Administration

   **Appendix B: Therapeutic Alternatives**
   *This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>estazolam</td>
<td>1 mg PO HS PRN</td>
<td>2 mg/day</td>
</tr>
<tr>
<td>eszopiclone (Lunesta®)</td>
<td>1 mg – 3 mg PO HS PRN</td>
<td>3 mg/day</td>
</tr>
<tr>
<td>Rozerem® (ramelteon)</td>
<td>8 mg PO HS PRN</td>
<td>8 mg/day</td>
</tr>
<tr>
<td>temazepam (Restoril®)</td>
<td>7.5 – 30 mg PO HS PRN</td>
<td>30 mg/day</td>
</tr>
<tr>
<td>triazolam (Halcion®)</td>
<td>0.25 mg PO HS PRN</td>
<td>0.5 mg/day</td>
</tr>
<tr>
<td>zaleplon (Sonata®)</td>
<td>10 mg PO HS PRN</td>
<td>20 mg/day</td>
</tr>
<tr>
<td>zolpidem (Ambien® and Ambien CR®)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>

   Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic. Formulary status may differ based on line of business and health plan; verify formulary status prior to redirection.

   **Appendix C: Contraindications/Boxed Warnings**
   - Contraindication(s): narcolepsy
   - Boxed warning(s): none reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insomnia</td>
<td>Recommended dose is 5 mg PO taken no more than once per night, immediately before going to bed, with at least 7</td>
<td>10 mg/day</td>
</tr>
<tr>
<td>Indication</td>
<td>Dosing Regimen</td>
<td>Maximum Dose</td>
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<td>hours remaining before the planned time of awakening. Dosage may be increased to 10 mg based on clinical response and tolerability. The maximum recommended dose is 10 mg once daily. Time to sleep onset may be delayed if taken with or soon after a meal.</td>
<td></td>
</tr>
</tbody>
</table>

VI. Product Availability
Tablets: 5 mg, 10 mg

VII. References

Reviews, Revisions, and Approvals
<table>
<thead>
<tr>
<th>Policy created; edited Appendix B therapeutic alternatives so that trial of zolpidem formulations (IR and CR) is equivalent to the trial of one alternative.</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>02.11.20</td>
<td>05.20</td>
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</tbody>
</table>

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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