Clinical Policy: Asenapine (Saphris)
Reference Number: CP.PMN.15
Effective Date: 08/15
Last Review Date: 08/16
Line of Business: Medicaid

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

Description
Asenapine (Saphris®) is an atypical antipsychotic.

FDA approved indication
Saphris is indicated:
- For the treatment of schizophrenia in adults
- For the treatment of bipolar I disorder
  - Acute monotherapy treatment of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age
  - Adjunctive treatment to lithium or valproate in adults
  - Maintenance monotherapy treatment in adults

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria.

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

I. Initial Approval Criteria
   A. Bipolar Disorder (must meet all):
      1. Diagnosis of bipolar disorder;
      2. Age ≥ 10 years;
      2. Failure of two PDL generic atypical antipsychotics agents at up to maximally indicated doses, each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced to ALL PDL generic antipsychotics;
      3. Dose does not exceed 20 mg per day (2 tablets/day).
      Approval duration: 12 months

   B. Schizophrenia (must meet all):
      1. Diagnosis of schizophrenia;
      2. Age ≥ 18 years;
      3. Failure of 2 PDL generic atypical antipsychotic agents at up to maximally indicated doses, each trialed for ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced to ALL PDL generic antipsychotics;
      4. Dose does not exceed 20 mg per day (2 tablets/day).
      Approval duration: 12 months

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C. Other diagnoses/indications
   1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III
      (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. All indications (must meet all):
      1. Currently receiving medication via Centene benefit, or documentation supports that
         member is currently receiving Saphris for bipolar or schizophrenia and has received
         this medication for at least 30 days;
      2. Documentation of positive response to therapy;
      3. If request is for a dose increase, new dose does not exceed 20 mg per day (2
         tablets/day).
      Approval duration: 12 months
   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports
         positive response to therapy.
      Approval duration: Duration of request or 12 months (whichever is less); or
      2. Refer to CP.XXXPMN.53## if diagnosis is NOT specifically listed under section III
         (Diagnoses/Indications for which coverage is NOT authorized)
      Approval duration: 12 months

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 policy –
      CP.PMN.53 or evidence of coverage documents;
   B. [Indications/diagnoses/situations in which drug is unsafe/ineffective] (This section
      should contain uses where the drug has been shown to be ineffective or unsafe or both.
      Do not list uses that are unproven, under investigation, or not studied here)

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   FDA: Food and Drug Administration
   PDL: preferred drug list

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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</thead>
<tbody>
<tr>
<td>Schizophrenia</td>
<td>5 - 10 mg twice daily</td>
<td>10 mg twice daily</td>
</tr>
<tr>
<td>Bipolar in adults</td>
<td>5 - 10 mg twice daily</td>
<td>10 mg twice daily</td>
</tr>
<tr>
<td>Bipolar in pediatric members</td>
<td>2.5 mg twice daily</td>
<td>10 mg twice daily</td>
</tr>
</tbody>
</table>

VI. Product Availability
    Sublingual tablets: 2.5 mg, 5 mg, and 10 mg

VII. Workflow Document
CLINICAL POLICY

Asenapine

VIII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New guideline created – replaces CP.PMN.56</td>
<td>08/15</td>
<td>08/15</td>
</tr>
<tr>
<td>Updated template and references.</td>
<td>05/16</td>
<td>08/16</td>
</tr>
<tr>
<td>Clinical changes to criteria</td>
<td>04/17</td>
<td>08/17</td>
</tr>
</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.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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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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