Clinical Policy: Pimavanserin (Nuplazid)
Reference Number: CP.PMN.140
Effective Date: 11.16.16
Last Review Date: 08.19
Line of Business: Commercial, Medicaid

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

Description
Pimavanserin (Nuplazid®) is an atypical antipsychotic.

FDA Approved Indication(s)
Nuplazid is indicated for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis.

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 Nuplazid is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Parkinson’s Disease Psychosis (must meet all):
      1. Diagnosis of hallucinations and delusions associated with Parkinson’s disease psychosis;
      2. Age ≥ 18 years;
      3. Dose does not exceed 34 mg per day.
      Approval duration:
      Medicaid – 12 months
      Commercial – Length of Benefit

   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 and CP.PMN.53 for Medicaid.

II. Continued Therapy
   A. Parkinson’s Disease Psychosis (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 34 mg per day.
      Approval duration:
      Medicaid – 12 months
Commercial – Length of Benefit

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 6 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 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 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
   Not applicable

   Appendix C: Contraindications/Boxed Warnings
   • Contraindication(s): hypersensitivity
   • Boxed warning(s): increased mortality in elderly patients with dementia-related psychosis

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Parkinson’s disease psychosis</td>
<td>34 mg PO QD</td>
<td>34 mg/day</td>
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VI. Product Availability
    Tablets: 10mg, 17 mg
    Capsules: 34 mg

VII. References
       Accessed May 1, 2019.

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Converted to new template. Minor changes to verbiage and grammar. References updated.</td>
<td>06.08.17</td>
<td>11.17</td>
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<tr>
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<td>3Q 2018 annual review: policies combined for Centene Medicaid and Commercial lines of business; replaces CP.PPA.19; age added; no significant changes; references reviewed and updated.</td>
<td>04.30.18</td>
<td>08.18</td>
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<td>No significant changes, updated product availability to include 10 mg tablet and 34 mg capsule per SDC.</td>
<td>12.19.18</td>
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<td>3Q 2019 annual review: No significant changes; references reviewed and updated.</td>
<td>05.01.19</td>
<td>08.19</td>
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**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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