Clinical Policy: Pimavanserin (Nuplazid)
Reference Number: CP.PPA.19
Effective Date: 08/16
Last Review Date: 08/176
Line of Business: Medicaid

~~Coding Implications~~
Revision Log

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**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**
Nuplazid is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

**Policy/Criteria**
*Provider must submit documentation ~~((~~which may include ~~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 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 Parkinson's disease;
~~1.~~2. Prescribed for treatment of ~~Treatment is for~~ psychotic symptoms including hallucinations and delusions;
~~2. Member has an established diagnosis of Parkinson's disease;~~
3. Prescribed by or in consultation with a neurologist or psychiatrist;
4. Dose does not exceed 34 mg/day (2 tablets/day).

**Approval duration: 12 months**

**B. 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. Parkinson's Disease Psychosis** (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Nuplazid for Parkinson's disease psychosis 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 34 mg/day (2 tablets/day).

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

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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.PMN~~XXX~~.53## if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**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~~;~~

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

~~Abbreviation: translation~~

~~N/A~~FDA: Food and Drug Administration

*Appendix B: Black Box Warning*

Nuplazid has a black box warning for increased mortality in elderly patients with dementia-related psychosis. -Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Nuplazid is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

**V. Dosage and Administration**

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Parkinson's disease psychosis | 34 mg, taken orally as two 17 mg tablets once daily | 34 mg per day |

**VI. Product Availability**

Tablets: 17 mg

**VII. Workflow Document**

Nuplazid WF.docx

Field Code Changed

**VIII. References**

1. Nuplazid Prescribing Information. San Diego, CA: Acadia Pharmaceuticals, Inc. April 2016. Available at: https://www.nuplazid.com/. Accessed March 2017.
2. Miyasaki JM, Shannon K, Voon V et al. Practice Parameter: evaluation and treatment of depression, psychosis, and dementia in Parkinson disease (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2006 Apr 11;66(7):996-1002.
~~2. Tarsy D. Management of comorbid problems associated with Parkinson disease. Hurtig HI, Dashe JF. (Ed), UpToDate. Waltham MA. Accessed June 2016.~~

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created. | 06/16 | 08/16 |
| ~~Non-c~~Clinical changes to criteria<br>- References updated | 03/17 | 08/17 |
| - | | |
| | | |

**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.



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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.