Clinical Policy: Pimavanserin (Nuplazid)

Reference Number: ERX.NPA.70
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions 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:
Commercial – Length of Benefit
Medicaid – 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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. 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 PO QD When administered with strong CYP3A4 inhibitors (e.g., ketoconazole): 10 mg PO QD	34 mg/day

VI. Product Availability

- Tablet: 10 mg
- Capsule: 34 mg

VII. References

1. Nuplazid Prescribing Information. San Diego, CA: Acadia Pharmaceuticals Inc; November 2020. Available at https://www.nuplazid.com/pdf/NUPLAZID_Prescribing_Information.pdf. Accessed March 23, 2021.
2. Seppi K, Chaudhuri KR, Coelho M, et al. Movement Disorders Society: Update on treatments for nonmotor symptoms of Parkinson's disease—An evidence-based medicine review. Movement Disorders. 2019; 34(2): 180-198.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.01.18	08.18
RT4: added new dosage form and strength of Nuplazid 34 mg capsules to the policy.	04.30.19	
3Q 2019 annual review: no significant changes; added Medicaid line of business with 12 month approval durations; references reviewed and updated.	05.01.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.27.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	03.23.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.