Clinical Policy: Pimavanserin (Nuplazid)

Reference Number: PA.CP.PPA.19
Effective Date: 01/18
Last Review Date: 11/17 Revision Log
Line of Business: Medicaid

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 office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of Pennsylvania Health and Wellness ® 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;
2. Prescribed for treatment of psychotic symptoms including hallucinations and delusions;
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 PA.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 Pennsylvania Health and Wellness benefit, or documentation supports that member is currently receiving Nuplazid for Parkinson's disease psychosis and has received this medication;or the Continuity of Care policy (PA.LTSS.PHAR.01) applies
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)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy. or the Continuity of Care policy (PA.LTSS.PHAR.01) applies

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to PA.CP.PMN.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 – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date