Effective Date: 12/2017

Revised: 7/2018, 10/2019

Reviewed: 12/2017, 7/2018, 10/2019, 06/2020, 3/2021

3/2022, 3/2023, 2/2024 Scope: Medicaid

NUPLAZID (pimavanserin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. PRECRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a board-certified neurologist.

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for initial treatment of hallucinations and delusions associated with Parkinson's disease psychosis when all of the following criteria are met:

- 1. Documented diagnosis of Parkinson's disease
- 2. Documented diagnosis of Parkinson's disease (PD) psychosis
- 3. Onset of psychosis must be after Parkinson's disease diagnosis (psychosis diagnosis was not present prior to Parkinson's Disease diagnosis)
- 4. Recent history of frequent moderate-to-severe hallucinations and delusions for at least one month in duration [Note: Frequent hallucinations and delusions are defined as psychotic events that occur at least once weekly]
- 5. The member has mild or no cognitive impairment as determined by physician's clinical diagnosis and/or cognitive impairment screening tests [e.g. Mini-Mental Status Examination (MMSE), Montreal Cognitive Assessment (MOCA)]
- 6. Prescriber has attempted to decrease member's dose of prescribed Parkinson's Disease (PD) medications to alleviate the potential cause of psychotic events
- 7. Member does not have evidence of a prolonged QT interval and/or is not taking medication that may prolong the QT interval
- 8. Member has been evaluated for, and does not have a diagnosis of, dementia-related psychosis



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9. Member has experienced an inadequate treatment response, intolerance, or contraindication to quetiapine and clozapine

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment of hallucinations and delusions associated with Parkinson's disease psychosis when the member has experienced improvement in psychotic symptoms (hallucinations and/or delusions) since starting therapy.

V. QUANTITY LIMIT

Nuplazid 10mg tablet: one tablet per day Nuplazid 34mg capsules: one capsule per day

VI. REFERENCES

- 1. Nuplazid [package insert]. San Diego, CA: Acadia Pharmaceuticals, Inc.; September 2023.
- 2. Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomized, placebo-controlled phase 3 trial. *Lancet.* 2014; 383:533-540.
- 3. Hoops S, Nazem S, et al. Validity of the MoCA and MMSE in the detection of MCI and dementia in Parkinson disease. *Neurology*. 2009; 73 (21): 1738-1745.

