Clinical Policy Title:	pimavanserin
Policy Number:	RxA.421
Drug(s) Applied:	Nuplazid®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Pimavanserin (Nuplazid®) is an atypical antipsychotic. It is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
pimavanserin (Nuplazid®)	Parkinson's disease psychosis	34 mg orally once daily, without titration	34 mg/day

Dosage Forms

- Tablet: 10 mg
- Capsule: 34 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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. Prescribed by or in consultation with a neurologist or psychiatrist;
3. Age ≥ 18 years;
4. Dose does not exceed 34 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member currently receiving medication that has been authorized by RxAdvance or member has

previously met initial approval criteria listed in this policy;
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: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CYP3A4: Cytochrome P450 3A4

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.

APPENDIX D: General Information
- QT Interval Prolongation: Increases in QT interval; avoid use with drugs that also increase the QT interval and in patients with risk factors for prolonged QT interval.
- The recommended dose of Nuplazid® when coadministered with strong CYP3A4 inhibitors (e.g., ketoconazole) is 10 mg, taken orally as one tablet once daily.
- Avoid concomitant use of strong or moderate CYP3A4 inducers with Nuplazid®.

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 June 28, 2021.
2. Nuplazid®. In: Lexicomp Online Drug Database [database on the Internet]. Hudson, Ohio: Lexicomp, Inc.; 2021 [updated May 15, 2021]. Available at: http://online.lexi.com. Subscription required to view. Accessed June 28, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy updated. 1. Formatting updated. 2. Policy Title updated. 3. Continued criteria for approval updated. 4. Approval duration updated. 5. Reference updated.	07/23/2020	09/14/2020

Policy was reviewed: 1. Dosing Information dosing regimen was updated to include “without titration…”. 2. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 3. Initial Approval Criteria I.A.2 was updated to include prescriber criteria, “Prescribed by or in consultation with a neurologist or psychiatrist”. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Appendix A was updated to include abbreviation CYP3A4. 6. Appendix C was updated to include Boxed Warnings, “Nuplazid® is not approved for the treatment…”. 7. Appendix D was updated to include “QT Interval Prolongation: Increases…”. 8. References were reviewed and updated.	06/28/2021	09/14/2021