



## Drug Coverage Policy

Effective Date ..... 06/15/2025

Coverage Policy Number.....IP0145

Policy Title.....Nuplazid

## Parkinson's Disease – Nuplazid

- Nuplazid® (pimavanserin capsules and tablets - Acadia)

### INSTRUCTIONS FOR USE

standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### Overview

Nuplazid, a selective serotonin 5-HT<sub>2A</sub> inverse agonist, is indicated for the treatment of hallucinations and delusions associated with **Parkinson's disease psychosis**.<sup>1</sup>

### Safety

Nuplazid has a Boxed Warning regarding increased mortality in elderly patients with dementia-related psychosis.<sup>1</sup> 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.

## Coverage Policy

## Policy Statement

Prior Authorization is required for prescription benefit coverage of Nuplazid. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Nuplazid as well as the monitoring required for adverse events and long-term efficacy, approval requires Nuplazid to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Pimavanserin (Nuplazid) is considered medically when the following are met:**

### FDA-Approved Indication

**1. Parkinson's Disease Psychosis.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient has hallucinations and delusions associated with Parkinson's disease psychosis; AND
- B)** Patient does not have dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis; AND
- C)** The medication is prescribed by or in consultation with a neurologist; AND
- D)** Preferred product criteria is met for the product(s) as listed in the below table(s)

### Employer Plans:

Product	Criteria
<b>Nuplazid</b> (pimavanserin)	<b>ONE of the following:</b> <ul style="list-style-type: none"><li>1. Failure, contraindication, intolerance to quetiapine or clozapine</li><li>2. If according to the prescriber, the patient is unable to use either quetiapine (Seroquel, generics) or clozapine (Clozaril, generics).</li><li>3. If the patient is currently taking Nuplazid or has taken Nuplazid at any time in the past.</li></ul>

### Individual and Family Plans:

Product	Criteria
<b>Nuplazid</b> (pimavanserin)	<b>ONE of the following:</b> <ul style="list-style-type: none"><li>1. Failure, contraindication, intolerance to quetiapine or clozapine</li><li>2. If according to the prescriber, the patient is unable to use either quetiapine (Seroquel, generics) or clozapine (Clozaril, generics).</li><li>3. If the patient is currently taking Nuplazid or has taken Nuplazid at any time in the past.</li></ul>

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Nuplazid for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. **Dementia-Related Psychosis.** Nuplazid prescribing information has a Boxed Warning regarding increased mortality in elderly patients with dementia-related psychosis.<sup>1</sup> Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

References

- 1. Nuplazid® capsules and tablets [prescribing information]. San Diego, CA: Acadia; January 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	<b>Parkinson’s Disease Psychosis.</b> <b>Added</b> ‘Patient does <u>not</u> have dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis’ <b>Updated</b> to move step through criteria to preferred product table. <b>Updated</b> preferred product table to include (1) patient is unable to use either quetiapine (Seroquel, generics) or clozapine (Clozaril,generics) and (2) patient is currently taking Nuplazid or has taken Nuplazid at any time in the past.	07/01/2024
Annual Review	No criteria changes.	6/15/2025

The policy effective date is in force until updated or retired.

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