



Drug Coverage Policy

Effective Date 7/1/2024
Coverage Policy Number.....IP0145
Policy Title.....Nuplazid

Parkinson’s Disease – Nuplazid

- Nuplazid® (pimavanserin capsules and tablets – Acadia)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain 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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

Overview

Nuplazid, a selective serotonin 5-HT_{2A} inverse agonist, is indicated for the treatment of hallucinations and delusions associated with **Parkinson’s disease psychosis**.¹

Safety

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

Medical Necessity Criteria

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.
 - D) Preferred product criteria is met for the product(s) as listed in the below table(s)

Employer Plans:

Product	Criteria
Nuplazid (pimavanserin)	ONE of the following: <ul style="list-style-type: none">1. Failure, contraindication, intolerance to quetiapine or clozapine2. If according to the prescriber, the patient is unable to use either quetiapine (Seroquel, generics) or clozapine (Clozaril, generics).3. If the patient is currently taking Nuplazid or has taken Nuplazid at any time in the past.

Individual and Family Plans:

Product	Criteria
Nuplazid (pimavanserin)	ONE of the following: <ul style="list-style-type: none">1. Failure, contraindication, intolerance to quetiapine or clozapine2. If according to the prescriber, the patient is unable to use either quetiapine (Seroquel, generics) or clozapine (Clozaril, generics).3. If the patient is currently taking Nuplazid or has taken Nuplazid at any time in the past.

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.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, 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.¹ 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; September 2023.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	Parkinson's Disease Psychosis. Added 'Patient does <u>not</u> have dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis' Updated to move step through criteria to preferred product table. Updated 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.	7/1/2024

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

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