

Prior Authorization Parkinson's Disease – Nuplazid® (pimavanserin capsules and tablets)

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Product Identifier(s)

Effective 1/1/23 to 2/27/23: 108944

Effective 2/28/23: 62924

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. 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.

National Formulary Medical Necessity

Cigna covers pimavanserin (Nuplazid®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended 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 individuals 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.

FDA Indication(s)

- **1. Parkinson's Disease Psychosis.** Approve for 1 year if the individual meets all of the following criteria (A, B, <u>and</u> C):
 - A) Individual has hallucinations and delusions associated with Parkinson's disease pychosis; AND
 - **B)** Individual does <u>not</u> have dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis; AND

C) Nuplazid is prescribed by or in consultation with a neurologist.

Conditions Not Covered

Pimavanserin capsules and tablets (Nuplazid®) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

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

Background

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 <u>not approved</u> for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

References

1. Nuplazid® capsules and tablets [prescribing information]. San Diego, CA: Acadia; November 2020.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	09/14/2022

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