

Drug and Biologic Coverage Policy



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Pimavanserin

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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.

Overview

This policy supports medical necessity review for pimavanserin (**Nuplazid**[®]).

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

Medical Necessity Criteria

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

Parkinson's Disease Psychosis. Individual meets **ALL** of the following criteria:

- A. Hallucinations or delusions associated with Parkinson's disease psychosis
- B. Medication is being prescribed by, or in consultation with, a neurologist
- C. Documentation of **ONE** of the following:
 - I. Documentation of failure, contraindication, or intolerance to **ONE** of the following: quetiapine or clozapine
 - II. Currently taking Nuplazid

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.

Reauthorization Criteria

Continuation of pimavanserin (Nuplazid) is considered medically necessary for Parkinson's Disease Psychosis when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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.

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 not approved 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.

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