Pharmacy Policy Bulletin

Title: Pimavanserin (Nuplazid®)

Policy #: Rx.01.163

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **pimavanserin (Nuplazid®)** as provided under the member's prescription drug benefit.

Description:

Psychosis is a frequent complication of Parkinson's disease (PD), and it is characterized mainly by visual hallucinations and delusions. Hallucinations are the most common manifestation, affecting up to 40 percent of patients with PD, particularly those at an advanced stage of illness. The adverse effects of antiparkinson medications are probably the most important cause of psychosis in patients with PD. Other triggers include infection, delirium, dementia, and psychoactive medications.

Management of psychosis in patients with PD involves identifying and treating the underlying causes and contributory factors, including general measures that are similar to the treatment of delirium. Stopping all potentially offending antiparkinsonian drugs is usually not an option for most patients, although dose reduction can frequently be accomplished with amelioration of hallucinations and little loss of drug-related benefit. Carbidopa/levodopa should be the last of a drug combination to be reduced, since it is the most effective antiparkinson agent and least likely to cause psychosis.

For patients with troublesome hallucinations or delusions despite antiparkinson medication adjustments, options include treatment with quetiapine, clozapine, or pimavanserin. The atypical neuroleptics clozapine and quetiapine may be helpful starting with low doses and incrementing slowly according to clinical response. Since quetiapine is easier to use than clozapine (no monitoring required) and is often effective, it should be the treatment of first choice.

The mechanism of action of pimavanserin in the treatment of hallucinations and delusions associated with Parkinson's disease psychosis is unknown. However, the effect of pimavanserin could be mediated through a combination of inverse agonist and antagonist activity at serotonin 5-HT2A receptors and to a lesser extent at serotonin 5-HT2C receptors. Pimvanaserin (Nuplazid®) is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Policy:

INITIAL CRITERIA: Pimavanserin (Nuplazid®) is approved when ALL of the following criteria are met:

1. Diagnosis of hallucinations and delusions associated with Parkinson's disease; and
2. Trial of dose adjustment or withdrawal of antiparkinsonian medications (anticholinergics, amantadine, dopamine agonists, COMT inhibitors, selegiline) prior to treatment with pimavanserin; and
3. Inadequate response or inability to tolerate clozapine or quetiapine

Initial Authorization: 6 months

REAUTHORIZATION CRITERIA: Pimavanserin (Nuplazid®) is re-approved when there is documentation of positive clinical response.

Reauthorization: 2 years

Black Box Warning as shown in the drug Prescribing Information:

Pimavanserin (Nuplazid®)

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

Pimavanserin is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Nuplazid® (pimavanserin) [package insert]. San Diego, CA. Acadia Pharmaceuticals, Inc. November 2020. Available at: https://www.nuplazid.com/sites/nuplazid/files/pdf/NUPLAZID_Prescribing_Information.pdf. Accessed March 30,2021.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand name	Generic name
Nuplazid®	pimavanserin

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	10.00
P&T Approval Date:	March 18,2021

Policy Effective Date: July 1, 2021

Next Required Review Date: March 18, 2022