MEDICAL MUTUAL®

Drug Policy

Policy:	Nuplazid (pimavanserin)	Annual Review Date: 05/16/2024 Last Revised Date: 05/16/2024

OVERVIEW

Nuplazid is indicated to treat hallucinations and delusions associated with Parkinson's disease psychosis (PDP). It has selective serotonin 5-HT_{2A} and 5-HT_{2C} activity and no dopamine receptor activity, thus making it a novel treatment for the atypical antipsychotic class. Nuplazid has a black box warning for increased mortality in elderly patients with dementia-related psychosis. Nuplazid may also prolong QT intervals. Use as an atypical antipsychotic for other, non-PDP, mental health indications has not been evaluated.

POLICY STATEMENT

This policy involves the use of Nuplazid. Prior authorization is recommended for pharmacy benefit coverage of Nuplazid. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Nuplazid be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nuplazid is recommended in those who meet the following criteria:

1. **Parkinson's Disease Psychosis (PDP), Initial Therapy**
   Criteria. *Patient must meet the following criteria (A, B,C, D, E and F):*
   A. The patient is 18 years of age or older; AND
   B. Patient has hallucinations and/or delusions associated with Parkinson's disease psychosis; AND
   C. Patient does not have dementia-related psychosis unrelated to the hallucinations and/or delusions associated with Parkinson's disease psychosis; AND
   D. Nuplazid is prescribed by or in consultation with a neurologist; AND
   E. Patient does not have a history of cardiac arrhythmias or QT prolongation; AND
   F. Patient will not use Nuplazid concomitantly with medications that prolong the QT interval; AND

G. Patient will not use Nuplazid concomitantly with other antipsychotic medications. May allow time period for switching.

2. Parkinson's Disease Psychosis (PDP), Continuation of Therapy
Criteria. *Patient must meet the following criteria (A, B and C):*

A. The patient is 18 years of age or older; AND
B. The patient has experienced an improvement in the frequency or severity of hallucinations and/or delusions associated with Parkinson's disease psychosis; AND
C. Nuplazid is prescribed by or in consultation with a neurologist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Nuplazid has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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