PIMAVANSERIN

Generic	Brand	HICL	GCN	Exception/Other
PIMAVANSERIN	NUPLAZID	43373		ROUTE = ORAL

***********Customer Service/PAC Alert************
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease psychosis and meets **ALL** of the following criteria?
   - Patient is 18 years of age or older
   - Medication is prescribed by or given in consultation with a physician specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as psychiatrist)

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **34mg capsules (GPID 44963): #30 capsules per 30 days.**
   - **17mg tablets (GPID 41264): #60 tablets per 30 days.**
   - **10mg tablets (GPID 44959): #30 tablets per 30 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline for **PIMAVANSERIN (Nuplazid)** requires a diagnosis of Parkinson's disease psychosis. The following criteria must also be met.
   - Patient is 18 years of age or older
   - The medication is prescribed by or given in consultation with a physician specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as a psychiatrist)

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the past 12 months of therapy, has the patient experienced an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment?

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **34mg capsules (GPID 44963): #30 capsules per 30 days.**
   - **17mg tablets (GPID 41264): #60 tablets per 30 days.**
   - **10mg tablets (GPID 44959): #30 tablets per 30 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline for **PIMAVANSERIN (Nuplazid)** renewal requires that the patient has experienced an improvement in psychosis symptoms from baseline during the past 12 months of therapy and demonstrates a continued need for treatment.

RATIONALE

Promote appropriate utilization of **pimavanserin** based on FDA approved indication.

Parkinson's disease (PD) has both motor and non-motor symptoms that can lead to disability, morbidity, and mortality. Parkinson's disease associated psychosis (PDP) is a non-motor symptom that develops at least a year after noticeable motor dysfunction. The psychotic symptoms of PDP are most commonly visual hallucinations, however patients may also experience sensory, somatic, or auditory hallucinations, as well delusions. Many times PDP develops as a result of medication(s) taken to aid with PD motor dysfunction. Current antipsychotic medications have been shown to worsen PD and motor dysfunction.

In clinical trials, pimavanserin was shown to significantly reduce The Scale for the Assessment of Positive Symptoms in Parkinson's Disease (SAPS-PD) scores leading to decreased caregiver burden, as well as improvement in sleep and daytime wakefulness. The SAPS-PD scale assesses the severity and frequency of hallucinations and delusions in PD patients; higher values indicate severer symptoms. A reduction in The Clinical Global Impression-Severity (CGI-S) and improvement scales (CGI-I) were also observed in patients both PDP treatment naïve, as well as those switched from currently available antipsychotics. Clinical trials were also able to show that pimavanserin is able to exhibit antipsychotic effects without negative impact on motor function as UPDRS parts II (activities of daily living) and III (motor function) scores demonstrated that pimavanserin was non-inferior to placebo. Extension studies demonstrated that treatment benefits are sustained over time. Clinical trials determined that an NNT of 11 was necessary to see a 50% reduction in psychotic symptoms.

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RATIIONALE (CONTINUED)

In clinical trials, pimavanserin was shown to improve scores on The Scale for the Assessment of Positive Symptoms in Parkinson's Disease (SAPS-PD), The Clinical Global Impression-Severity (CGI-S) and improvement scales (CGI-I) scores, and caregiver burden scale.

DOSAGE

The recommended dosage of Nuplazid is 34mg orally once daily, without titration, taken with or without food. Reduce dose to 10mg once daily when administering with a strong CYP3A4 inhibitor.

FDA APPROVED INDICATION

Nuplazid (pimavanserin) is indicated as treatment of hallucinations and delusions associated Parkinson's disease psychosis.
Boxed warning:

- Increased risk of death in dementia-related psychosis treated with antipsychotic drugs.
- Nuplazid is not approved for the treatment of dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

REFERENCES

- Nuplazid [Prescribing Information]. San Diego, CA. Arcadia Pharmaceuticals Inc. June 2018.
- Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomized, placebo-controlled phase 3 trial. *The Lancet*. 2014; 383 (9916): 533-540.
- Tabares W. Pimavanserin for Patients with Parkinson's Disease Psychosis. Available at: https://pharmpractice.ku.edu/journal-club-digest/pimavanserin-patients-parkinson%E2%80%99s-disease-psychosis. Accessed April 8, 2016
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- Fernandez HH, Aarsland D, Fe´nelon G, et al. Scales to Assess Psychosis in Parkinson's Disease: Critique and Recommendations. *Mov Disord.* 2008; 23(4): 484-500. pdf

Library	Commercial	NSA
Yes	Yes	No

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