pimavanserin (Nuplazid®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO053

Description

Pimavanserin (Nuplazid) is an orally administered is an atypical antipsychotic that works as a selective serotonin inverse agonist with an unknown mechanism of action.

Length of Authorization

- Initial: six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit	DDID
pimavanserin (Nuplazid)	34 mg capsules	Parkinson's disease psychosis	30 capsules/30 days	203479, 203276
	17 mg tablets		60 tablets/30 days	192903, 192710
	10 mg tablets		30 tablets/ 30 days	203478, 203281

Initial Evaluation

I. Pimavanserin (Nuplazid) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. The medication is prescribed by or in consultation with a neurologist; **AND**
   C. A diagnosis of **Parkinson's disease psychosis** with symptoms of hallucinations and delusions when the following are met:
      1. Symptoms of hallucinations and delusions have continued after reductions in current medications for Parkinson's disease or reductions in medications are not possible based on provider attestation; **AND**
      2. Treatment with clozapine (Clozaril®) has been ineffective, intolerable or contraindicated

II. Pimavanserin (Nuplazid) is considered investigational when used for all other conditions, including but not limited to the diagnosis of:
   A. Alzheimer's disease
   B. Schizophrenia

Renewal Evaluation

I. Noted reduction in delusions and hallucinations.

Supporting Evidence

I. Pimavanserin (Nuplazid) is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis for patients 18 years of age and older.

II. Pimavanserin (Nuplazid) was studied in a 6-week, randomized, placebo-controlled, parallel-group study in 199 patients with a diagnosis of Parkinson's disease (PD) and psychotic symptoms.
    - The primary efficacy outcome was the change from baseline to week 6 in a PD-adapted scale for the assessment of positive symptoms (SAPS-PD).
    - A positive effect was seen on both hallucination and delusion components of the SAPS-PD for pimavanserin versus placebo [-3.06 (-4.91, -1.2)]. Although statistically significant, the clinical relevance of this result is unclear.
    - No difference in motor function was observed between pimavanserin and placebo.

III. Pimavanserin (Nuplazid) was studied in multiple unpublished clinical trials that either failed to demonstrate efficacy or were terminated early due to trial failure.

IV. Pimavanserin (Nuplazid) was FDA-approved under the breakthrough therapy and priority review designation where preliminary clinical evidence indicated pimavanserin (Nuplazid) may demonstrate substantial improvement over current available therapies. In addition, the FDA-medical reviewer recommended against FDA-approval.

V. Clozapine has been studied in two four-week, placebo-controlled trials, as well as, two smaller trials comparing clozapine and quetiapine. Clozapine demonstrated improved global impression scores, improved psychotic symptom assessment scores, and similar motor and cognitive function compared with patients on placebo.

VI. The Movement Disorder Society rated clozapine as more efficacious compared to quetiapine which was deemed to have insufficient evidence, and does not make any recommendation on pimavanserin (Nuplazid).

References

1. Pimavanserin (Nuplazid®) [Prescribing Information]. San Diego, CA: Acadia Pharmaceuticals, Inc. 2016.
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4. Merims D, Balas M, Peretz C, Shabtai H, Giladi N. Rater-blinded, Prospective Comparison: Quetiapine Versus Clozapine for Parkinson's Disease Psychosis. *Clin Neuropharmacol*. 2006; 26:331-337.

5. Morgante L, Epifanio A, Spina E, et al. Quetiapine and Clozapine in Parkinsonian Patients with Dopaminergic Psychosis. *Clin Neuropharmacol*. 2004; 27:153-156.
6. Pollak P, Tison F, Rascol O, et al. Clozapine in drug induced psychosis in Parkinson's disease: a randomized, placebo controlled study with open follow up. *J Neurol Neurosurg Psychiatry*. 2004; 75:689–695.
7. Seppi K, Weintraub D, Coelho M, et al. The Movement Disorder Society Evidence-Based Medicine Review Update: Treatments for the Non-Motor Symptoms of Parkinson's Disease. *Mov Disord*. 2011; 26(0 3): S42–S80.
8. UpToDate, Inc. Clinical manifestations of Parkinson disease. UpToDate [database online]. Waltham, MA. Updated 01/12/2016. Available at: http://www.uptodate.com/home/index.html. [Accessed 08/14/2019].
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Policy Implementation/Update:

Date Created	July 2016
Date Effective	August 2016
Last Updated	September 2019
Last Reviewed	September 2019

Action and Summary of Changes	Date
Transition from criteria to policy: Included requirements to attempt dose reduction in parkinson's medications, and specified what members must try and fail.	September 2019