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Federal Employee Program.

NUPLAZID (pimavanserin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Nuplazid is an atypical antipsychotic used in patients with psychosis due to Parkinson's disease. Parkinson's disease is a neurodegenerative brain disorder where cell death causes a reduction in the amount of dopamine being secreted. This may result in a variety of effects including motor problems as well as neuropsychiatric symptoms (1).

Regulatory Status

FDA-approved indications: Nuplazid is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis (2).

Nuplazid has a boxed warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. 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 (2).

Nuplazid is not recommended in patients with hepatic impairment or severe renal impairment ($\text{CrCL} \geq 30 \text{ mL/min}$ Cockcroft-Gault). Nuplazid has not been evaluated in these patient populations (2).

For patients with hallucinations or delusions despite antiparkinsonian medication adjustments, first-line options for treatment are quetiapine and clozapine (3).

Safety and effectiveness of Nuplazid in pediatric patients under 18 years of age have not been established (2).

Summary

Nuplazid is an atypical antipsychotic used in patients with psychosis due to Parkinson's disease. Parkinson's disease is a neurodegenerative brain disorder where cell death causes a reduction in the amount of dopamine being secreted. This may result in a variety of effects including motor problems as well as neuropsychiatric symptoms. Psychosis such as hallucinations or delusions may be the result of excessive dopamine from Parkinson's disease medications. Safety and effectiveness of Nuplazid in pediatric patients under 18 years of age has not been established (1-2).



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Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Nuplazid while maintaining optimal therapeutic outcomes.

References

1. National Parkinson Foundation. Understanding Parkinson's: Non-Movement Symptoms. Retrieved from: <https://www.parkinson.org/Understanding-Parkinsons/Non-Movement-Symptoms>.
2. Nuplazid [package Insert]. San Diego, CA: ACADIA Pharmaceuticals Inc.; September 2023.
3. UpToDate. Waltham, MA: Wolters Kluwer Health; 2019. <https://www.uptodate.com/home>.