Medical Policy

BlueCross BlueShield of Kansas
An independent licensee of the Blue Cross Blue Shield Association

Title: Selective Serotonin Inverse Agonist (SSIA)

- **Prime Therapeutics will review Prior Authorization requests**

  Prior Authorization Form:
  http://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth-6440KS-SSIA.pdf

  Link to Drug List (Formulary):
  http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.shtml

Professional	**Institutional**
Original Effective Date: December 1, 2016	Original Effective Date: December 1, 2016
Revision Date(s): December 1, 2016	Revision Date(s): December 1, 2016
Current Effective Date: December 1, 2016	Current Effective Date: December 1, 2016

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

DESCRIPTION

The intent of the Selective Serotonin Inverse (SSIA) prior authorization (PA) and Quantity Limit (QL) program is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and according to dosing recommended in product labeling. The program requires the trial of guideline recommended clozapine and quetiapine prior to approval of the requested agent. The program allows for approval for those who are unable to use clozapine or quetiapine due to FDA labeled contraindication, intolerance, or hypersensitivity. The program will not approve for patients who have an FDA labeled contraindication to the requested agent. The program will approve for doses within the set limit. Doses above the set limit will be approved if the requested quantity is below the FDA limit and cannot be dose optimized or when the quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Requests will be reviewed when patient specific documentation is provided.

Target Drugs

- **Nuplazid** (pimavanserin)

FDA Approved Indications and Dosage[1]

Agent	Indication	Dosage & Administration
Nuplazid™ (pimavanserin)	Treatment of hallucinations and delusions associated with Parkinson's disease psychosis	Recommended dose is 34 mg, taken orally as two 17 mg tablets once daily, without titration

POLICY

Prior Authorization and Quantity Criteria for Approval

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   a. The patient has a diagnosis of hallucinations or delusions associated with Parkinson's disease psychosis
      OR
   b. Other FDA approved indication
   AND
2. ONE of the following:
   a. The patient's medication history includes the use of clozapine or quetiapine
      OR
   b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to clozapine or quetiapine
   AND

3. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
   AND
4. ONE of the following:
   a. The quantity requested is less than or equal to the program quantity limit
      OR
   b. The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength
      OR
   c. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 12 months

Agent	Contraindication(s)
Nuplazid (pimavanserin)	None

Brand (generic)	Quantity Limit Per Day
Nuplazid (pimavanserin)	
17 mg tablet	2 tablets

RATIONALE

Guidelines

Clozapine and quetiapine should be considered for Parkinson's patients and psychosis. Clozapine is associated with agranulocytosis that may be fatal. The absolute neutrophil count must be monitored.[2] Pimavanserin is not yet included in treatment guidelines.

Efficacy

Pimavanserin's efficacy in hallucinations and delusions associated with Parkinson's disease psychosis was studied in a 6-week, randomized, placebo-controlled, parallel-group study with 199 patients. Pimavanserin was statistically significantly superior to placebo in decreasing the frequency and/or severity of hallucinations and delusions in patients with PDP as measured by central, independent, and blinded raters using the PD-adapted Scale for the Assessment of Positive Symptoms (SAPS-PD) scale. An effect was seen on both the hallucinations and delusions components of the SAPS-PD scale.

Safety

Pimavanserin does not have any contraindications but does have the following black box warnings:[1]

- 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.

REVISIONS

12-01-2016	Policy added to the bcbsks.com web site on 11-01-2016. Policy effective 12-01-2016.

REFERENCES

1. Nuplazid prescribing information. ACADIA Pharmaceuticals Inc. April 2016.
2. Practice Parameter: Evaluation and treatment of depression, psychosis, and dementia in Parkinson disease (an evidence-based review) Report of the Quality Standards Subcommittee of the American Academy of Neurology. American Academy of Neurology. NEUROLOGY. 2006;66:996–1002.