SAPHRIS® (asenapine)

LENGTH OF AUTHORIZATION:

Initial Therapy: Up to 3 months

Continuation of therapy: Up to Six Months

CLINICAL NOTES:
Asenapine (Saphris®) is an atypical antipsychotic indicated for both acute and maintenance treatment of schizophrenia. Asenapine is also indicated as monotherapy or adjunctive therapy with lithium or valproate for the treatment of manic or mixed episodes associated with bipolar I disorder.

INITIAL REVIEW FOR PEDIATRIC PATIENTS WITH BIPOLAR DISORDER:
- Patient must be ≥ 10 years old
- Patient must have a diagnosis of bipolar disorder
- Trial of at least two preferred atypical antipsychotics with a minimum 30 day treatment period (i.e. risperidone, aripiprazole)
- Patient must be capable of following strict administration instructions including sublingual administration and no food or drink for ten minutes after administration

INITIAL REVIEW CRITERIA FOR ADULTS:
- Patient must be ≥18 years old.
- Patient must have a diagnosis of schizophrenia or Bipolar I disorder
- Patient must be capable of following strict administration instructions including sublingual administration and no food or drink for ten minutes after administration
- For the treatment of schizophrenia, patient must have a history of trial and failure of at least:
  - Two preferred atypical antipsychotics with a minimum 30-day treatment period with each agent.

- For the treatment of Bipolar I disorder, patient must have failed to respond or be intolerant to an adequate trial (at least 30 days with therapeutic blood levels) of two of the following:
  - Lithium OR
  - Valproic Acid OR
  - Combination of a mood stabilizer and one preferred atypical antipsychotic OR
  - Combination of two or more mood stabilizers

CONTINUATION OF THERAPY FOR PEDIATRIC PATIENTS
- Documentation of satisfactory response to asenapine must be submitted.
CONTINUATION OF THERAPY FOR ADULTS

- **Schizophrenia:**
  - As maintenance therapy in patients with satisfactory response to asenapine in the acute phase who had a previous trial and failure of two other atypical antipsychotics as described above.

- **Bipolar I Disease- Manic or Mixed:**
  - Following remission of an acute bipolar manic or mixed episode, patients may remain at particularly high risk of relapse for a period of up to six months.
  - Evaluate every 3 months for the need for continuation of therapy after the acute management.
  - The clinical trials for asenapine in this setting were 3-week long trials.
  - The best empirical evidence for maintenance treatment of manic or mixed bipolar I patients includes lithium and valproate.
  - Approve for maintenance therapy of manic or mixed bipolar I disorder only in patients who previously qualified for and received asenapine during the acute phase and are currently receiving lithium and/or valproate without satisfactory results.

**DOSING & ADMINISTRATION:**

**PEDIATRIC PATIENTS 10-17:**

- The recommended dose of SAPHRIS is 2.5mg-10mg twice daily in pediatric patients 10-17 years of age, and dose may be adjusted for individual response and tolerability.
- The starting dose of SAPHRIS is 2.5mg twice daily. The dose can be increased to 5mg twice daily after 3 days, then to 10mg twice daily (maximum dose) after 3 additional days.
- If the initial recommended escalation schedule is not followed, pediatric patients (10-17) tend to be more sensitive to dystonia.

**ADULTS:**

- The recommended starting dose and maintenance dose for the treatment of schizophrenia is 5 mg sublingually twice daily to a maximum of 10 mg sublingually twice daily in adults.
- The initial dose for acute manic or mixed episodes of Bipolar I disease is 10 mg sublingually twice daily. Maintenance doses, used as an adjunct to lithium and valproate, are 5-10 mg sublingually twice daily with a maximum dose of 10 mg twice daily.
- Patients should not eat or drink for ten minutes after dose administration.
- Dosage Form: 5mg, 10 mg sublingual tablets (NOTE: Saphris must be administered sublingually; when taken by mouth and swallowed, less than two percent of the drug becomes available in the systemic circulation)