



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 28, 2015 April 29, 2015, May 6, 2015, November 6, 2015

SAPHRIS® (asenapine)

LENGTH OF AUTHORIZATION:

Initial Therapy: Up to 3 months

Continuation of therapy: Up to Six Months

CLINICAL NOTES:

Saphris® (asenapine) is an atypical antipsychotic indicated for both acute and maintenance treatment of schizophrenia. Saphris® (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 Saphris® (asenapine) must be submitted.



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CONTINUATION OF THERAPY FOR ADULTS

- Schizophrenia:
 - As maintenance therapy in patients with satisfactory response to Saphris® (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 Saphris® (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 Saphris® (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® (asenapine) must be administered sublingually; when taken by mouth and swallowed, less than two percent of the drug becomes available in the systemic circulation).