

Division: Pharmacy Services	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 28, 2015 May 19, 2022

SAPHRIS® (asenapine)

LENGTH OF AUTHORIZATION:

Initial Therapy: Up to 6 Months

Continuation of therapy: Up to One Year

INITIAL REVIEW CRITERIA:

- 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 be ≥ 18 years old; AND
- Patient must have a history, within the past 365 days of trial and failure of a preferred atypical antipsychotic with a minimum 30-day treatment period.

For the treatment of Bipolar I disorder

- Patient must be ≥ 10 years old; AND
- 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

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING & ADMINISTRATION:

- Available as: 2.5mg, 5mg, 10 mg sublingual tablets.
- Refer to product labeling <https://www.accessdata.fda.gov/scripts/cder/daf/>