



Division: Pharmacy Services	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 28, 2015 May 19, 2022, January 24, 2024

## 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  $\geq 18$  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  $\geq 10$  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/>