Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 29, 2021 May 19, 2022

LYBALVI™ (olanzapine and samidorphan) tablets

LENGTH OF AUTHORIZATION: Up to one year

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must not be using opioids.
- Patient must have a diagnosis of schizophrenia **OR** bipolar I disorder.
- **For the treatment of schizophrenia**, 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 have failed to respond or be intolerant to an adequate trial (at least 30 days with therapeutic blood levels) of olanzapine and one 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 has met initial review criteria.
- A positive clinical response is documented with therapy.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg tablets.
- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/

Note: Lybalvi can precipitate opioid withdrawal in patients who are dependent on opioids. Prior to initiating Lybalvi, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.