Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 29, 2021 May 19, 2022, January 24, 2024, November 15, 2024, February 26, 2025, March 18, 2025, April 4, 2025

LYBALVI™ (olanzapine and samidorphan) tablets

LENGTH OF AUTHORIZATION: Up to one year

THIS MEDICATION MAY RECEIVE APPROVAL UNDER TWO CRITERIA

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 AND trial and failure of at least two of the following with a minimum 30-day treatment period:
  - Caplyta
  - Rexulti
  - Vraylar
- **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 preferred treatment options (e.g. Lithium, quetiapine, lamotrigine, divalproex, aripiprazole).
- **For patients currently being treated with Lybalvi™**, patient must have a fill history within the past 180 days.

ALTERNATE REVIEW CRITERIA

- Clinical documentation of medical necessity because:
  - The patient has a diagnosis of schizophrenia, schizotypal or delusional disorder and meets the following:
    - The drug product or medication of a similar drug class is prescribed for the treatment of schizophrenia or schizotypal or delusional disorders; **-AND-**
    - Prior authorization has been granted previously for the prescribed drug; **-AND-**
    - The medication was dispensed to the patient during the previous 12 months

CONTINUATION OF THERAPY:

- Patient has met initial review criteria.
- A positive clinical response is documented with therapy.
- Patient has not experienced any treatment-restricting adverse effects (e.g. neuroleptic malignant syndrome (NMS), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), severe metabolic changes).
- Dosing is appropriate as per labeling or is supported by compendia.

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 29, 2021 May 19, 2022, January 24, 2024, November 15, 2024, February 26, 2025, March 18, 2025, April 4, 2025

DOSING AND ADMINISTRATION:

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

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.