ALASKA MEDICAID
Prior Authorization Criteria

Lybalvi™
(olanzepine/samidorphan)

FDA INDICATIONS AND USAGE[1]

Lybalvi™ is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of Schizophrenia and Bipolar I disorder in adults. Bipolar I disorder includes the acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate and for maintenance monotherapy treatment.

APPROVAL CRITERIA[1,2,3]

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a psychiatrist **AND**;
3. Patient meets DSM-5 criteria and has a diagnosis of Schizophrenia or Bipolar I disorder **AND**;
4. A baseline metabolic panel has been documented (including glucose, lipid, and patient's baseline weight)and will continue to be monitored throughout therapy **AND**;
5. Patient will be monitored for development of signs/symptoms related to neuroleptic malignant syndrome (NMS), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), body temperature dysregulation, severe cognitive or motor impairment, seizures, dysphagia, severe anticholinergic effects, and hyperprolactinemia **AND**;
6. Patient has tried and failed at least 2 atypical antipsychotics for a period of at least 4 weeks.

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient has dementia-related psychosis **OR**;
3. Patient is using opioids **OR**;
4. Patient is undergoing acute opioid withdrawal **OR**;
5. Patient is taking a strong CYP3A4 inducer or levodopa and dopamine agonists **OR**;
6. Patient has recently had a myocardial infarction (MI) or unstable cardiovascular disease.

CAUTIONS[1]

- See Package Insert: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213378s000lbl.pdf

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 1 year if the patient has shown disease improvement and stabilization and has not had any adverse effects (I.E. severe metabolic changes, tardive dyskinesia, etc.)

QUANTITY LIMIT

- 30 tablets (1 tablet per day)

REFERENCES / FOOTNOTES:

1. Lybalvi™[Package Insert]. Alkermes, Inc., Walham, MA. May 2021. Accessed at:https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213378s000lbl.pdf Accessed: August 13, 2021.
2. Potkin SG, Junovac J, Silverman BL, et al. Efficacy and safety of a combination of olanzapine and samidorphan in adult patients with an acute exacerbation of schizophrenia: outcomes from the randomized, phase 3 ENLIGHTEN-1 Study. J Clin Psychiatry. 2020; 81(2): 19m12769. DOI: 10.4088/JCP.19m12769.
3. Correll et al. Effects of olanzapine combined with samidorphan on weight gain in schizophrenia: A 24-week phase 3 study. Am J Psychiatry. 2020; (177)12: 1168-1178. DOI: 10.1176/appi.ajp.2020.19121279.