UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2271-3
Program	Prior Authorization/Medical Necessity
Medication	Lybalvi™ (olanzapine/samidorphan)*
P&T Approval Date	2/2022, 2/2023, 11/2023
Effective Date	2/1/2024

1. Background:

Lybalvi (olanzapine/samidorphan)* is FDA approved for the treatment of schizophrenia and for the treatment of bipolar 1 disorder for acute treatment of manic or mixed episodes as monotherapy, as an adjunct to lithium or valproate, and as maintenance monotherapy.

For the treatment of schizophrenia, the selection of which antipsychotic medication to use for an individual patient with schizophrenia should be made based on patient clinical factors and the side effect profiles of antipsychotic drugs. With the exception of clozapine for patients with refractory symptoms, there is not convincing evidence to favor one antipsychotic over the others based on efficacy.

For the treatment of bipolar disorder acute manic or mixed episodes, treatment selection depends on the severity of illness and associated features, and patient preference. Second-generation (atypical) antipsychotics are generally preferred over first-generation (typical) antipsychotics because of their favorable side effect profile. No one antipsychotic is preferred over the others.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Lybalvi*** will be approved based on **ALL** the following criteria:

   a. Submission of medical records documenting **both** of the following:

      (1) The patient has a diagnosis of one of the following:

         (a) schizophrenia
         (b) bipolar 1 disorder

-AND-

      (2) The patient has a history of failure, contraindication or intolerance to a trial of at least TWO of the following:

         (a) aripiprazole
         (b) olanzapine
         (c) quetiapine IR or XR
         (d) risperidone
         (e) ziprasidone

-AND-

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b. The patient has a documented history of weight gain of greater than or equal to 10% of their baseline weight after initiating antipsychotic medication

Authorization will be approved for 12 months.

B. Reauthorization

1. **Lylbalvi*** will be approved based on the following criterion:

   a. Documentation of positive clinical response to therapy.

Authorization will be approved for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Lybalvi is typically excluded from coverage.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4. References:

1. Lybalvi [package insert]. Waltham, MA: Alkermes, Inc; May 2021.
2. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Bipolar Disorder Second Editions. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf
3. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia Third Edition. Available at: https://psychiatryonline.org/doi/10.1176/appi.books.9780890424841

Program	Prior Authorization/Medical Necessity – Lybalvi*
Change Control	
Date	Change
2/2022	New program.
2/2023	Annual review with no changes.
11/2023	No changes.

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