# Drug Coverage Policy

**Effective Date.....4/15/2024**
**Coverage Policy Number.....IP0368**

# Lybalvi

- Lybalvi™ (olanzapine and samidorphan tablets)

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## Medical Necessity Criteria

**Lybalvi is considered medically necessary when the following criteria is met:**

1. **Treatment of EITHER Schizophrenia or Bipolar 1 Disorder.** Individual meets **BOTH** of the following criteria:
    A. Age 18 years or older
    B. Documentation that the individual is NOT using opioids or undergoing acute opioid withdrawal
    C. Preferred product criteria is met for the products listed in the below table(s)

**Employer Plans:**

| Product | Criteria |
|---|---|
| **Lybalvi** (olanzapine and samidorphan) | **Standard/Performance/Value/Advantage/Total Savings Plans:**<br>Documentation of **ONE** of the following:<br>1. Failure, contraindication, or intolerance to **TWO** of the following:<br>A. aripiprazole<br>B. asenapine<br>C. olanzapine<br>D. paliperidone ER<br>E. quetiapine ER<br>F. risperidone<br>G. ziprasidone<br>2. Individual is currently receiving Lybalvi |

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Reauthorization Criteria

Continuation of Lybalvi is considered medically necessary for **ALL** covered diagnoses when the above medical necessity criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 12 months.
Reauthorization approval duration: up to 12 months.

## Conditions Not Covered

Any other use is considered not medically necessary.

## Background

**OVERVIEW**
Lybalvi, a combination of olanzapine (an atypical antipsychotic) and samidorphan (an opioid antagonist), is indicated for the treatment of 1) schizophrenia in adults; and 2) bipolar I disorder in adults for the acute treatment of manic or mixed episodes as monotherapy and as an adjunct to lithium or valproate, as well as for maintenance monotherapy treatment.[1]

Guidelines do not address Lybalvi. The American Psychiatric Association (APA) published recent guidelines for the treatment of schizophrenia (2020). The APA recommends that patients with schizophrenia be treated with an antipsychotic medication and monitored for effectiveness and AEs. The choice of pharmacological treatment depends on many factors that are specific to an individual patient. With the exception of clozapine, there is no conclusive efficacy data that a

particular antipsychotic will have notable superiority compared with another. The APA does not formulate a preference of when to use a first generation vs. a second generation antipsychotic. A specific second generation antipsychotic is not cited as favored. Regarding metabolic abnormalities, comparing the multiple second generation atypical antipsychotics, olanzapine and clozapine are the agents noted to be the most associated with weight gain, hyperlipidemia, and glucose abnormalities. Second generation antipsychotics with a reduced potential for weight gain are aripiprazole and ziprasidone.[2]

## References


1. Lybalvi tablets [prescribing information]. Waltham, MA: Alkermes; May 2021.
2. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. Third Edition. August 2020. Available at: http://psychiatryonline.org/guidelines. Accessed on June 24, 2021.


## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Annual Revision | No criteria changes | 4/15/2024 |

The policy effective date is in force until updated or retired.