MEDICAL MUTUAL®

Drug Policy

Policy:	Lybalvi (olanzapine and samidorphan)	Annual Review Date: 11/21/2024 Last Revised Date: 11/21/2024

OVERVIEW

Lybalvi is a single-tablet combination treatment indicated as a maintenance monotherapy for the treatment of schizophrenia in adults and for the treatment of bipolar I disorder in adults. Samidorphan serves as a means of mitigating the weight-gain associated with the use of olanzapine.

POLICY STATEMENT

This policy involves the use of Lybalvi. Prior authorization is recommended for pharmacy benefit coverage of Lybalvi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Lybalvi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Lybalvi be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lybalvi is recommended in those who meet the following criteria:

1. <u>Schizophrenia</u>

Criteria. *Patient must meet the following criteria*

- **A.** The patient is 18 years of age or older; AND
- **B.** Lybalvi is prescribed by or in consultation with a psychiatrist or a physician who specializes in mental health care; AND
- **C.** Patient does not have a known opioid use disorder or is dependent on opioids for a chronic health condition
- **D.** One of the following criteria is met (I <u>or</u> II):
  - **I.** Previous trial of generic olanzapine demonstrated positive response, but unacceptable weight gain while on therapy [documentation required]; OR
  - **II.** Documented trial of two oral, generic second-generation antipsychotics at maximally tolerated doses for at least 4 weeks.

Initial Approval/ Extended Approval.
A) *Initial Approval: 1 year (365 days)*
B) *Extended Approval: 1 year (365 days)*

2. Bipolar I Disorder
Criteria. *Patient must meet the following criteria*

- **A.** The patient is 18 years of age or older; AND
- **B.** Lybalvi is prescribed by or in consultation with a psychiatrist or a physician who specializes in mental health care; AND
- **C.** Patient does not have a known opioid use disorder or is dependent on opioids for a chronic health condition
- **D.** One of the following criteria is met (I or II):
  - **I.** Previous trial of generic olanzapine demonstrated positive response, but unacceptable weight gain while on therapy [documentation required]; OR
  - **II.** Documented trial of two oral, generic second-generation antipsychotics at maximally tolerated doses for at least 4 weeks.

Initial Approval/ Extended Approval.
A) *Initial Approval: 1 year (365 days)*
B) *Extended Approval: 1 year (365 days)*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lybalvi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Lybalvi® [prescribing information]. Waltham, MA: Alkermes Inc; May 2021.