LYBALVI®

olanzapine and samidorphan

5 mg/10 mg · 10 mg/10 mg · 15 mg/10 mg

20 mg/10 mg tablets

Supporting Your Patients' Access to LYBALVI® Treatment

IMPORTANT: Healthcare providers are responsible for keeping current and complying with all applicable insurer requirements and for the selection of codes that accurately reflect their patient's condition and the services rendered. Healthcare providers also are responsible for the accuracy of all claims and related documentation submitted for reimbursement. Alkermes does not guarantee coverage or reimbursement. Under no circumstances will Alkermes, Inc., or its affiliates, employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages that may arise from, or be incurred in connection with, the information provided here or any use thereof.

INDICATIONS

LYBALVI is indicated for the treatment of:

- Schizophrenia in adults
- Bipolar I disorder in adults
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

IMPORTANT SAFETY INFORMATION

Boxed Warning: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. LYBALVI is not approved for the treatment of patients with dementia-related psychosis.

Please see additional Important Safety Information on the following pages and full Prescribing Information, including **Boxed Warning**.

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IMPORTANT SAFETY INFORMATION

Contraindications: LYBALVI is contraindicated in patients who are using opioids or are undergoing acute opioid withdrawal. If LYBALVI is administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for the contraindications for these products.

Please see additional Important Safety Information on the following pages and full Prescribing Information, including **Boxed Warning**.

Prior Authorization Support

Prior authorization support for LYBALVI is available through CoverMyMeds®

CoverMyMeds® is a third-party platform external to Alkermes.

- Automates the prior authorization process online with insurance-specific forms and information
- *Healthcare provider offices* can quickly find and submit a prior authorization via the healthcare provider portal or via certain EHR platforms
- *Pharmacists* can also send a prior authorization request to your office for you to complete and submit
- *Health plans* can provide determinations via the CoverMyMeds® portal to both your office and the local pharmacy
- CoverMyMeds® live agents can help you navigate the appeal process by providing health plan-specific appeal forms for you to complete and return to the plan, in the event coverage is denied
- Available at no cost to your office

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To electronically submit a prior authorization:

1. Find a prior authorization via the healthcare provider portal at **go.covermymeds.com/provider**
2. Complete and submit the prior authorization request
3. Attach all necessary documentation

For questions, call **1-866-452-5017**.

IMPORTANT SAFETY INFORMATION

Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis, including stroke, transient ischemia attack, and fatalities. See Boxed Warning above.

Precipitation of Severe Opioid Withdrawal in Patients who are Physiologically Dependent on Opioids: LYBALVI can precipitate opioid withdrawal in patients who are dependent on opioids, which can lead to an opioid withdrawal syndrome, sometimes requiring hospitalization. LYBALVI is contraindicated in patients who are using opioids or undergoing acute opioid withdrawal. Prior to initiating LYBALVI, there should be at least a 7-day opioid-free interval from last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids. Explain the risks associated with precipitated withdrawal and the importance of giving an accurate account of last opioid use to patients and caregivers.

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Helpful information

In some cases, a letter of medical necessity may be required for LYBALVI to be covered.

The checklist for medical necessity and appeal letters can also be easily downloaded at **LYBALVIaccess.com**

Checklist for a Letter of Medical Necessity for LYBALVI

Information you may wish to include in a letter of medical necessity

- ☐ Patient's diagnosis and code, condition, and history
- ☐ Previous therapies the patient has taken for the symptoms associated with the disease and the patient's response to previous therapies
- ☐ Brief description of the patient's recent symptoms and condition
- ☐ Summary of the professional opinion clearly stating the rationale for prescribing LYBALVI for this patient
- ☐ Documents that support your rationale for LYBALVI treatment, including the patient's medical records

These checklists are not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage or reimbursement for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coverage and reimbursement vary significantly by payer, patient, and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers.

IMPORTANT SAFETY INFORMATION

Vulnerability to Life-Threatening Opioid Overdose: Attempting to overcome opioid blockade with high or repeated doses of exogenous opioids could lead to life-threatening or fatal opioid intoxication, particularly if LYBALVI therapy is interrupted or discontinued subjecting the patient to high levels of unopposed opioid agonist as the samidorphan blockade wanes. Inform patients of the potential consequences of trying to overcome the opioid blockade and the serious risks of taking opioids concurrently with LYBALVI or while transitioning off LYBALVI. In emergency situations, if a LYBALVI-treated patient requires opioid treatment as part of anesthesia or analgesia, discontinue LYBALVI. Opioids should be administered by properly trained individual(s) and patient should be continuously monitored in a setting equipped and staffed for cardiopulmonary resuscitation. Patients with a history of chronic opioid use prior to treatment with LYBALVI may have decreased opioid tolerance if LYBALVI therapy is interrupted or discontinued. Advise patients that this decreased tolerance may increase the risk of opioid overdose if opioids are resumed at the previously tolerated dosage.

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Checklist for Appealing a Claim Denial for LYBALVI Coverage

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Consider reviewing this checklist when your patient is requesting an appeal of a denied insurance claim for LYBALVI

- ☐ Review the Explanation of Benefits (EOB) to determine the reason for the claim denial
- ☐ If additional information is requested, submit it immediately or within the required time frame for processing
- ☐ If the denial was due to a technical error, amend it and submit a corrected claim
- ☐ Verify the appeals process with the health insurance company
  - Does the health insurance company require use of a specific form?
  - Can the appeal be conducted over the telephone?
  - If the appeal must be submitted in writing, to whom should it be directed?
  - What information must be included with the appeal (eg, a copy of the original claim, EOB, letter of medical necessity, or other documentation)?
  - How long does the appeals process usually take?
  - How will the health insurance company communicate the appeals decision?
- ☐ Review the appeal request for accuracy and completeness, including patient identification numbers, coding, and additional information requested
- ☐ Consider requesting that the payer have a psychiatrist or other designated provider who is familiar with treating patients with this condition review the appeal
- ☐ File the appeal as soon as possible and within filing time limits
- ☐ Reconcile responses to the appeal promptly and thoroughly to ensure an appeal has been processed appropriately
- ☐ Record appeals result (eg, payment amount or if further action is required)

IMPORTANT SAFETY INFORMATION

Neuroleptic Malignant Syndrome, a potentially fatal reaction. Signs and symptoms include hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation, intensive symptomatic treatment, and close monitoring.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), a potentially fatal condition reported with exposure to olanzapine, a component of LYBALVI. Symptoms include a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. Discontinue if DRESS is suspected.

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CARE SUPPORT

To request services, please enroll your patient by filling out a LYBALVI Care Support patient enrollment form at **LYBALVI.com**

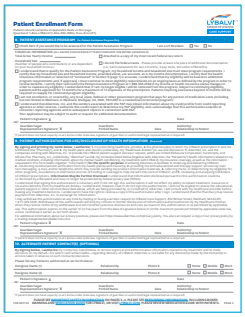
You can also call **1-844-LYBALVI (1-844-592-2584)**, Monday through Friday, 9:00 AM to 8:00 PM ET.

Patient Support Services

For additional support or for those patients who do not have insurance coverage, LYBALVI Care Support may be able to help

LYBALVI Care Support can

- Conduct a benefits verification
- Enroll qualified patients who are uninsured and meet eligibility criteria into the Patient Assistance Program, which can provide LYBALVI at no cost for up to 12 months
  - Patient must provide proof of household size and annual gross income, and certify that they meet financial and insurance criteria
  - LYBALVI must be prescribed by a licensed US healthcare provider and delivered to a location within the 50 states (excluding Puerto Rico and US territories)
  - Patient must be prescribed LYBALVI for an on-label use and be 18 years of age or older


Patient Enrollment Form

LYBALVI CARE SUPPORT PATIENT ENROLLMENT FORM

IMPORTANT SAFETY INFORMATION

Metabolic Changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Any patient treated with LYBALVI should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required anti-diabetic treatment despite discontinuation of the suspect drug. Measure weight and assess fasting glucose and lipids when initiating LYBALVI and monitor periodically.

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LYBALVI Co-pay Savings Program

Commercially insured eligible patients pay

$0 for the first 3 fills of LYBALVI*

After the first 3 fills, each refill may cost as little as $20 with a maximum savings of $450 per 30-day supply*

Provide your patients with the LYBALVI Co-pay Savings Program brochure. To request more, contact your Sales Representative.

Patients who already have a Co-pay Savings Program Card will need to confirm eligibility and activate it at **LYBALVI.com** or by calling **1-855-724-3546**.

Eligible patients who do not have a card can download the Co-pay Savings Program Card at **LYBALVI.com** or request a card by calling **1-855-724-3546**.

*Maximum savings limit applies; patients' out-of-pocket expenses may vary. Maximum 30-day supply per fill for the first 3 fills. Beginning at fill 4, a maximum savings of $450 per 30-day supply will be provided towards the cost of the LYBALVI prescription. Health plan requirements for a prior authorization and/or step therapies must be attempted prior to using this co-pay offer. Patient must be 18 years of age or older and have a prescription for LYBALVI. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Offer not valid for cash paying patients. Please see full Program Terms and Conditions on page 8.

Please see additional Important Safety Information on the following pages and full Prescribing Information, including Boxed Warning.

LYBALVI Co-pay Savings Program Terms and Conditions

Eligibility for Alkermes-sponsored Co-pay Savings: This offer is only available to commercially insured patients 18 years or older with a LYBALVI prescription that is consistent with the Prescribing Information. Health plan requirements for a prior authorization and/or step therapies must be attempted prior to using this co-pay offer. This offer is not available to patients who are enrolled in, or covered by, any local, state, federal or other government program that pays for any portion of medication costs, including but not limited to Medicare, including Medicare Part D or Medicare Advantage plans; Medicaid, including Medicaid Managed Care and Alternative Benefit Plans under the Affordable Care Act; Medigap; VA; DOD; TRICARE; or a residential correctional program. Patients who become eligible for any government program that pays for any portion of medication costs will no longer be eligible for this program.

Authorization and Additional Terms of Use: By using this offer, you authorize the LoyaltyScript® Program to share your prescription information with CoverMyMeds so that CoverMyMeds may contact your healthcare provider to request submission of information to support coverage of your LYBALVI prescription by your health insurance plan. This offer is not conditioned on any past, present, or future purchase, including refills. Alkermes reserves the right to rescind, revoke, or amend this offer, program eligibility, and requirements at any time without notice. This offer is limited to one per patient, may not be used with any other offer, is not transferable, and may not be sold, purchased or traded, or offered for sale, purchase, or trade. Void where prohibited by law. Program may be subject to plan benefit design requirements. Program Administrator or its designee will have the right upon reasonable prior written notice, during normal business hours, and subject to applicable law, to audit compliance with this program.

IMPORTANT SAFETY INFORMATION

Tardive Dyskinesia (TD): Risk of developing TD (a syndrome of potentially irreversible, involuntary, dyskinetic movements) and the likelihood it will become irreversible increases with the duration of treatment and the cumulative dose. The syndrome can develop after a relatively brief treatment period, even at low doses, or after discontinuation. Given these considerations, LYBALVI should be prescribed in a manner that is most likely to reduce the risk of tardive dyskinesia. If signs and symptoms of TD appear, drug discontinuation should be considered.

Orthostatic Hypotension and Syncope: Monitor orthostatic vital signs in patients who are vulnerable to hypotension, patients with known cardiovascular disease, and patients with cerebrovascular disease.

Falls: LYBALVI may cause somnolence, postural hypotension, and motor and sensory instability, which may lead to falls, and consequently, fractures or other injuries. Assess patients for risk when using LYBALVI.

Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases): Perform complete blood counts in patients with a history of a clinically significant low white blood cell (WBC) count or history of leukopenia or neutropenia. Discontinue LYBALVI if clinically significant decline in WBC occurs in the absence of other causative factors.

Dysphagia: Use LYBALVI with caution in patients at risk for aspiration.

Seizures: Use LYBALVI with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

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IMPORTANT SAFETY INFORMATION

Potential for Cognitive and Motor Impairment: Because LYBALVI may cause somnolence, impair judgment, thinking, or motor skills, caution patients about operating hazardous machinery, including motor vehicles, until they are certain that LYBALVI does not affect them adversely.

Body Temperature Dysregulation: Use LYBALVI with caution in patients who may experience conditions that increase core body temperature (e.g., strenuous exercise, extreme heat, dehydration, or concomitant use with anticholinergics).

Anticholinergic (Antimuscarinic) Effects: Olanzapine, a component of LYBALVI, was associated with constipation, dry mouth, and tachycardia. Use LYBALVI with caution with other anticholinergic medications and in patients with urinary retention, prostatic hypertrophy, constipation, paralytic ileus or related conditions. In postmarketing experience, the risk for severe adverse reactions (including fatalities) was increased with concomitant use of anticholinergic medications.

Hyperprolactinemia: LYBALVI elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.

Risks Associated with Combination Treatment with Lithium or Valproate: If LYBALVI is administered with lithium or valproate, refer to the lithium or valproate Prescribing Information for a description of the risks for these products.

Most common adverse reactions observed in clinical trials were:

- *Schizophrenia (LYBALVI):* weight increased, somnolence, dry mouth, and headache
- *Bipolar I Disorder, Manic or Mixed Episodes (olanzapine):* asthenia, dry mouth, constipation, increased appetite, somnolence, dizziness, tremor
- *Bipolar I Disorder, Manic or Mixed Episodes, adjunct to Lithium or Valproate (olanzapine):* dry mouth, dyspepsia, weight gain, increased appetite, dizziness, back pain, constipation, speech disorder, increased salivation, amnesia, paresthesia

Concomitant Medication: LYBALVI is contraindicated in patients who are using opioids or undergoing acute opioid withdrawal. Concomitant use of LYBALVI is not recommended with strong CYP3A4 inducers, levodopa and dopamine agonists. Reduce dosage of LYBALVI when using with strong CYP1A2 inhibitors. Increase dosage of LYBALVI with CYP1A2 inducers. Use caution with diazepam, alcohol, other CNS acting drugs, or in patients receiving anticholinergic (antimuscarinic) medications. Monitor blood pressure and reduce dosage of antihypertensive drug in accordance with its approved product labeling.

Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with LYBALVI. Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to LYBALVI during pregnancy.

Renal Impairment: LYBALVI is not recommended for patients with end-stage renal disease (eGFR of <15 mL/minute/1.73 m^2).

To report SUSPECTED ADVERSE REACTIONS, contact Alkermes at 1-888-235-8008 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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