



Access Support Q&A

A guide for healthcare professionals

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.

Will my patients need a prior authorization for LYBALVI®?

We are committed to supporting your patients' access to LYBALVI. Each insurer determines its own policies, and prior authorization may sometimes be required. Prior authorization support is available through CoverMyMeds®, which may help you navigate the prior authorization process.

Is there information available on submitting a prior authorization for LYBALVI?

CoverMyMeds® offers free prior authorization services. To electronically submit a prior authorization for LYBALVI for many plans

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

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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What if coverage is denied?

In the event that coverage is denied, you may assist your patient in appealing the denial. Some health plans have appeal forms, and CoverMyMeds® has health plan-specific appeal forms that you can complete and return to the plan. In addition, you will see the specific requirements for the appeal as communicated by the insurance plan.

In some cases, a letter of medical necessity from the physician may be required for a medication to be covered. To support patient access to LYBALVI treatment, a checklist for a letter of medical necessity or letter of appeal is available at LYBALVIaccess.com

Does Medicare or Medicaid cover LYBALVI?

For patients with Medicare, coverage for LYBALVI may vary among Medicare plans. Patients with Medicare should speak to their benefits administrator, insurer, or plan provider to confirm coverage for LYBALVI.

For patients with Medicaid, benefits vary by state. Patients with Medicaid may contact their state Medicaid agency to confirm coverage for LYBALVI.

For additional support, LYBALVI Care Support can conduct a benefits verification for your patient. To request services, please enroll your patient by using the enrollment form at LYBALVI.com

In some cases, a letter of medical necessity from the physician may be required for a medication to be covered. To support patient access to LYBALVI treatment, a checklist for a letter of medical necessity or letter of appeal is available at LYBALVIaccess.com

I have patients who do not have any insurance and can't afford LYBALVI.

What are their options?

Alkermes is committed to helping patients gain access to LYBALVI. Patients who do not have insurance may apply to the Patient Assistance Program, which provides access to LYBALVI at no cost for up to 12 months to patients who meet program eligibility criteria.

- 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

Patients may apply by completing a LYBALVI Care Support 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.

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.

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What will my patient's co-pay be for LYBALVI?

For Medicare/Medicaid patients

The co-pay for LYBALVI may vary among Medicare Part D or Medicare Advantage plans. Patients with Medicare should speak to their benefits administrator, insurer, or plan provider to confirm the co-pay for LYBALVI.

Medicaid benefits vary by state. Patients with Medicaid may contact their state Medicaid agency to confirm the co-pay for LYBALVI.

For commercially insured patients

The out-of-pocket cost for LYBALVI can vary and depends on your patient's insurance plan. Depending on the plan and benefit design, patients may be asked for a copayment, coinsurance, or the full amount for each prescription. Commercially insured eligible patients can enroll in the LYBALVI Co-pay Savings Program and pay \$0 for the first 3 fills. Beginning with fill 4, each refill may cost as little as \$20 with a maximum savings of \$450 per 30-day supply.

Certain conditions apply to the LYBALVI Co-pay Savings Program:

- 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 at [LYBALVI.com/copayterms](https://www.lybalvi.com/copayterms) and at the end of this brochure

When you prescribe LYBALVI, please be sure to provide your commercially insured patients with a LYBALVI Co-pay Savings Program brochure. Patients must confirm eligibility and activate the Co-pay Savings Program Card by visiting [LYBALVIcopay.com](https://www.lybalvi.com) or calling **1-855-724-3546**.

Qualifying patients can also enroll and download the Co-pay Savings Program Card directly from our website at [LYBALVIcopay.com](https://www.lybalvi.com)

IMPORTANT SAFETY INFORMATION

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

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For commercially insured patients

Where can my patients enroll in the LYBALVI Co-pay Savings Program?

Your Alkermes Representative can provide your practice with LYBALVI Co-pay Savings Program brochures to give to your patients. Patients may also enroll online at LYBALVIcopay.com

Do patients need to enroll in LYBALVI Care Support to use the LYBALVI Co-pay Savings Program?

Patients do not need to enroll in LYBALVI Care Support for the Co-pay Savings Program. Patients will need to activate their Co-pay Savings Program Card by visiting LYBALVIcopay.com or calling **1-855-724-3546**. Patients may also enroll online at LYBALVIcopay.com

Do patients need to bring their LYBALVI Co-pay Savings Program Card with them each time they refill their prescription?

When patients bring the LYBALVI Co-pay Savings Program Card to the pharmacy along with their LYBALVI prescription for the first time, they can ask their pharmacist whether their LYBALVI Co-pay Savings Program Card information can be stored on file for future use.

Also, patients who enroll online have an option of either receiving the LYBALVI Co-pay Savings Program Card via email or by text message to save to their mobile wallet, allowing them to have their card with them whenever needed.

IMPORTANT SAFETY INFORMATION

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.

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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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.

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.

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.

Please see additional Important Safety Information on the following page and full [Prescribing Information](#), including **Boxed Warning**.

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 m²).

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

Please see full [Prescribing Information](#), including **Boxed Warning**.

LYBALVI® (olanzapine and samidorphan) 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 LYBALVI Co-pay Savings Program Terms and Conditions for Co-pay Card: 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.

To the Patient: Present this card and prescription for LYBALVI to the pharmacist to participate in this program. When using this card, you certify that you understand the program rules and terms and conditions and that you meet, or are the legal guardian of a patient who meets, the program eligibility requirements. 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. **For questions about your eligibility or benefits, if your insurance has changed, or if you wish to discontinue your participation, call the LYBALVI Co-pay Savings Program at 1-855-820-9624 (8:00 AM-8:00 PM EST, Monday-Friday).**

To the Pharmacist: When using this card, you certify that you have not submitted and will not submit a claim for reimbursement under any local, state, federal, or other government program for this prescription. Submit transaction to McKesson Corporation using BIN 610524. Submit commercial insurance as primary coverage, input co-pay savings card information as secondary coverage, and transmit using the COB segment of the NCPDP transaction. Applicable discounts will be displayed in the transaction response. Acceptance of this card and your submission of claims for LYBALVI are subject to the LoyaltyScript® Program terms and conditions posted at www.mckesson.com/mprstnc. Patient is not eligible if patient is 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, Medicaid, Medigap, VA, DOD, TRICARE, or a residential correctional program. The LYBALVI Co-pay Savings Program card is not valid for use with any other prescription drug discount or cash cards for LYBALVI. Claims submitted utilizing the program are subject to audit or validation. **For questions regarding setup, claim transmission, patient eligibility, or other issues, call the LoyaltyScript® Program for the LYBALVI Co-pay Savings Program at 1-855-821-2977 (8:00 AM-8:00 PM EST, Monday-Friday).**

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.

Please see full [Prescribing Information](#), including **Boxed Warning**.



For more information, go to
LYBALVIhcp.com