




Actor portrayal.

# Access Guide

  
**LYBALVI**<sup>®</sup>  
olanzapine and samidorphan  
5 mg/10 mg • 10 mg/10 mg • 15 mg/10 mg  
20 mg/10 mg tablets

## Resources for Supporting Your Patients' Access to LYBALVI<sup>®</sup>

### 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 throughout the brochure and on pages [18-19](#) and full [Prescribing Information](#), including Boxed Warning.



This guide provides detailed information about access to LYBALVI®, including available resources, some helpful reminders, and answers to FAQs



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# Resources are available to support your patients' access to LYBALVI®

Support for your patients' access to LYBALVI is available through:



## LYBALVI Care Support Administered by ASPN Pharmacies

**Dedicated support** throughout the prescription journey

- Benefits verification
- Prior authorization/appeal education and coordination
- Co-pay savings program enrollment for eligible patients
- Prescription triage to dispensing pharmacy per patient choice
- Provider/office communication
- Patient communication
- Refill reminders\*
- Dispensing pharmacy communication



## CoverMyMeds

Guides HCP offices through the **prior authorization** and appeal process

- Prior authorization/appeal support
- Provider/office communication

More information about each fulfillment pathway is available in this resource, organized by the tabs on the right.

\*Refill reminders for ASPN mail order pharmacies only.  
HCP=healthcare professional.

## 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.

### Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis,

including stroke, transient ischemia attack, and fatalities. See Boxed Warning.

Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full Prescribing Information, including Boxed Warning.







# LYBALVI® Care Support Administered by ASPN Pharmacies provides dedicated patient support throughout the prescription journey

ASPN Pharmacies is a third-party non-dispensing pharmacy that administers the LYBALVI Care Support Program

## LYBALVI Care Support

### How it works

|  |  |  |
|--|--|--|
| 1<br>   | If your patients would like ASPN services, send LYBALVI prescriptions to ASPN Pharmacies via your EHR, or call or fax in the prescription  | <p><b>Inform your patients that they will receive a call or text from ASPN Pharmacies. Confirm that an accurate phone number is included in the prescription.</b></p> <p>Within your EHR, search for <b>"ASPN Pharmacies"</b> or search by ZIP Code, state, NPI, or NCPDP number</p> <p><b>ZIP Code:</b> 07039</p> <p><b>State:</b> New Jersey</p> <p><b>NPI:</b> 1538590690</p> <p><b>NCPDP:</b> 3147863</p> <p>You can also send in a prescription via <b>phone or fax</b> Monday through Friday from 9 AM to 8 PM ET</p> <p><b>Phone:</b> 1-844-LYBALVI (1-844-592-2584)</p> <p><b>Fax:</b> 1-877-FAX-LYBV (1-877-329-5928)</p> |
| 2<br>   | Within 2 business hours, ASPN Pharmacies contacts your patient   |  |
| 3<br> | ASPN Pharmacies conducts a benefits verification, provides prior authorization and appeal process education and coordination, and offers the LYBALVI Co-pay Savings Program to eligible patients |  |
| 4<br> | ASPN Pharmacies sends the prescription to the dispensing pharmacy of your patient's choice for pickup or home delivery. Refill reminders are offered to eligible patients                        |  |

LYBALVI Care Support provides prior authorization and appeal process education and coordination. Your office would first submit a prior authorization request, which may include a letter of medical necessity. You may also need to submit a letter of appeal if the claim is denied. For tips, see the Prior Authorization & Appeals Reminders tab of this guide.

EHR=electronic health record; NCPDP=National Council for Prescription Drug Programs; NPI=National Provider Identifier.

## 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.

Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full Prescribing Information, including Boxed Warning.





# LYBALVI® Care Support Administered by ASPN Pharmacies acts as a single point of contact



## Helpful considerations

- Refer to the *ICD-10-CM* codes on the following page, which may apply to patients appropriate for LYBALVI
- ASPN Pharmacies will communicate directly with you via fax, phone, or an easy and accessible portal
- Inform your patients that they will receive a call or text from ASPN Pharmacies within 2 business hours. Confirm that an accurate phone number is included in the prescription

**For questions about  
this dedicated support**

**Call 1-844-LYBALVI (1-844-592-2584)**  
Monday through Friday, 9 AM to 8 PM ET

**ASPN PHARMACIES ACTS AS A SINGLE POINT OF CONTACT  
FOR PROVIDERS, PATIENTS, DISPENSING PHARMACIES, AND PAYERS**

FDA=US Food and Drug Administration; *ICD-10-CM*=*International Classification of Diseases, Tenth Revision, Clinical Modification*.

## 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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# Considerations when using ICD-10-CM diagnosis codes

Claims submitted for LYBALVI should include at least one ICD-10-CM diagnosis code to indicate the patient's condition. Diagnosis codes should represent the condition as supported by the patient's medical record. The diagnosis codes listed below may apply to patients for whom LYBALVI may be appropriate.

## Examples of ICD-10-CM Diagnosis Codes for Schizophrenia

|              |                                |               |                            |
|--------------|--------------------------------|---------------|----------------------------|
| <b>F20.0</b> | Paranoid schizophrenia         | <b>F20.5</b>  | Residual schizophrenia     |
| <b>F20.1</b> | Disorganized schizophrenia     | <b>F20.89</b> | Other schizophrenia        |
| <b>F20.2</b> | Catatonic schizophrenia        | <b>F20.9</b>  | Schizophrenia, unspecified |
| <b>F20.3</b> | Undifferentiated schizophrenia |               |                            |

## Examples of ICD-10-CM Diagnosis Codes for Bipolar I Disorder

|               |   |               |   |
|---------------|---|---------------|---|
| <b>F31.10</b> | Bipolar disorder, current episode manic without psychotic features, unspecified | <b>F31.63</b> | Bipolar disorder, current episode mixed, severe, without psychotic features |
| <b>F31.11</b> | Bipolar disorder, current episode manic without psychotic features, mild        | <b>F31.64</b> | Bipolar disorder, current episode mixed, severe, with psychotic features    |
| <b>F31.12</b> | Bipolar disorder, current episode manic without psychotic features, moderate    | <b>F31.70</b> | Bipolar disorder, currently in remission, most recent episode unspecified   |
| <b>F31.13</b> | Bipolar disorder, current episode manic without psychotic features, severe      | <b>F31.73</b> | Bipolar disorder, in partial remission, most recent episode manic           |
| <b>F31.2</b>  | Bipolar disorder, current episode manic severe with psychotic features          | <b>F31.74</b> | Bipolar disorder, in full remission, most recent episode manic              |
| <b>F31.60</b> | Bipolar disorder, current episode mixed, unspecified                            | <b>F31.77</b> | Bipolar disorder, in partial remission, most recent episode mixed           |
| <b>F31.61</b> | Bipolar disorder, current episode mixed, mild                                   | <b>F31.78</b> | Bipolar disorder, in full remission, most recent episode mixed              |
| <b>F31.62</b> | Bipolar disorder, current episode mixed, moderate                               |               |   |

**IMPORTANT:** Healthcare providers are responsible for keeping current and complying with all applicable coverage requirements and for the selection of diagnosis and procedure 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. Additional insurance requirements may apply and healthcare providers should always contact the insurer directly to obtain complete and current information regarding coverage of LYBALVI.

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.

**Reference:** 2024 Code Tables, Tabular and Index. 2024 ICD-10-CM. Centers for Medicare & Medicaid Services. Published 2024. Accessed March 8, 2024. <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>

## Important Safety Information

### Neuroleptic Malignant Syndrome,

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

Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full Prescribing Information, including Boxed Warning.

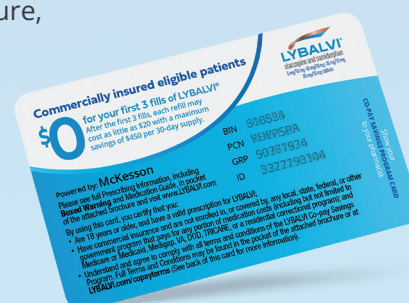




# LYBALVI® Co-pay Savings Program

Provide your patients with the LYBALVI Co-pay Savings Program brochure, which includes the Co-pay Savings Program Card. To request more brochures, contact your Alkermes Representative.

**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



For illustrative purposes only.

No activation process needed.

Eligible patients can also receive their Co-pay Savings Program Card at [LYBALVI.com/copay](https://www.LYBALVI.com/copay) or by texting **"COPAY"** to **45286**.

**Over 90% of commercial patients** utilizing the LYBALVI Co-pay Savings Program Card pay \$20 or less for LYBALVI\*



[LYBALVI.com/copay](https://www.LYBALVI.com/copay)

The LYBALVI Co-pay Savings Program ("Program") is only available to commercially insured patients who are 18 years or older with a valid LYBALVI prescription. Health plan requirements for a prior authorization and/or step therapies must be attempted, and an outcome documented, regardless of the outcome, prior to using this co-pay offer. **This Program is not available to patients who are enrolled in Medicare, Medicaid, or other federal or state healthcare programs.** Maximum savings limit applies; patients' out-of-pocket expenses may vary. Maximum 30-day supply per fill for the first 3 fills in the Program. Beginning at fill 4 and thereafter, a maximum savings of \$450 per 30-day supply will be provided towards the cost of the LYBALVI prescription. **Please see full terms and conditions at [www.LYBALVI.com/copayterms](https://www.LYBALVI.com/copayterms). 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 ET, Monday-Friday).**

By texting "COPAY" to 45286, patients will receive texts with the LYBALVI Co-pay Savings Program eligibility requirements and Terms and Conditions. If the patient is eligible and agrees to the Terms and Conditions, they will receive a co-pay savings card by text. Message/data rates may apply. Message frequency varies. Patients may opt out of receiving texts at any time by texting "STOP." Consent to SMS messages not required to participate. For alternate enrollment visit [www.LYBALVI.com](https://www.LYBALVI.com)

\*Based on out-of-pocket costs for commercially insured patients in the LYBALVI Co-pay Savings Program from April 2023 to June 2023.

## Important Safety Information

### 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.

Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full Prescribing Information, including Boxed Warning.





# CoverMyMeds can help you automate the prior authorization process

CoverMyMeds

If you are not selecting dedicated support through LYBALVI® Care Support Administered by ASPN Pharmacies, you still have the option of using CoverMyMeds for support through the prior authorization process

## To electronically submit a prior authorization to CoverMyMeds

- 1 Find a prior authorization via the healthcare provider portal at [go.covermymeds.com/provider](https://go.covermymeds.com/provider)
- 2 Complete and submit the prior authorization request
- 3 Attach all necessary documentation



Actor portrayal.

Time to a decision: **<24 HOURS for 89%** of electronic prior authorization submissions, on average\*



\*Based on CoverMyMeds LYBALVI data from October 2022 through October 2023 and not representative of all prior authorization submissions. Prior authorization through CoverMyMeds is not a guarantee of approval.

## 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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# CoverMyMeds offers live support for your prior authorization questions

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

CoverMyMeds can help support you with prior authorizations and appeals.  
**For questions or to schedule an online portal demo,**



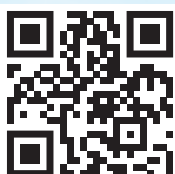
**VISIT**  
[go.covermymeds.com/  
provider](https://go.covermymeds.com/provider)



**CALL**  
1-866-452-5017



**LIVE CHAT AT**  
[covermymeds.com](https://covermymeds.com)



Live support is available

**Monday–Friday, 8 AM–11 PM ET and Saturday, 8 AM–6 PM ET**

## 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.

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# Prior authorization reminders

Each insurer determines its own policies, and a prior authorization may sometimes be required for a medication. In some cases, a letter of medical necessity from the physician may be required for coverage. To support patient access, the following checklists are provided to help facilitate communications with health insurance companies to support a prior authorization, a formulary exception request, a medical exception, or an appeal of a denied claim for coverage of LYBALVI®.

## Information you may wish to include when completing a prior authorization request

Consider including the following information and documentation to help support a prior authorization, formulary exception request, or a medical exception:

- ☐ Patient's diagnosis and ICD-10-CM diagnostic code
- ☐ Patient's condition and medical history
- ☐ Previous drug therapies the patient has taken for the symptoms associated with the disease and the patient's response to previous therapies
- ☐ Summary of 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



### Tips for submitting a prior authorization request

- Confirm that the insurance coverage on file for your patient is up to date prior to conducting a benefits verification
- Make sure you understand the patient's health plan coverage criteria for LYBALVI and for the prior authorization process
- Double-check that you completed all necessary information on the prior authorization form and that you are providing any required supporting documentation
- After submitting the prior authorization, ask about expected processing time
- Keep the patient informed throughout the process
- Follow up as needed if you do not hear back in a timely manner
- Document all steps, including any calls or messages, submission materials, approval date, and expiration date

## Important Safety Information

### 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.

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# Letter of medical necessity reminders

## Information you may want to include in a letter of medical necessity

- ☐ Patient's diagnosis and *ICD-10-CM* diagnostic 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 professional opinion clearly stating the rationale for the treatment recommended for this patient
- ☐ Documents that support your rationale for the recommended treatment, including the patient's medical records



### Tips for submitting a letter of medical necessity

- Confirm that the insurance coverage you have on file for your patient is up to date
- Check if the payer has specific forms you need to fill out when submitting a letter of medical necessity for LYBALVI®
- Include the patient's full insurance information, name, and date of birth, and your office's contact information in all your communications with the payer

**IMPORTANT:** Healthcare providers are responsible for keeping current and complying with all applicable coverage requirements and for the selection of diagnosis and procedure 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. Additional insurance requirements may apply and healthcare providers should always contact the insurer directly to obtain complete and current information regarding coverage of LYBALVI. 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.

## Important Safety Information

### 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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# Letter of appeal reminders

**If your patient's plan denies a submitted claim, you may consider requesting an appeal. This checklist may help your appeal process**

- ☐ 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 fulfillment is required)

## Important Safety Information

### Potential for Cognitive and Motor Impairment:

Because LYBALVI® may cause somnolence, and may 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).

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# Letter of appeal reminders (continued)



## Tips for submitting an appeal

- Denials may happen due to prior authorization request errors, including lack of supporting documentation, incomplete forms, or failure to understand and meet the plan-specific coverage criteria for LYBALVI®
- Submit the appeal in a timely manner after receiving the denial
- Check if the payer has specific forms you need to fill out or processes you need to follow when submitting an appeal for LYBALVI
- Align closely to the language used in the denial letter when writing your response
- Include the patient's full insurance information, name, and date of birth, and your office's contact information in all your communications with the payer
- Follow up as needed if you do not hear back in a timely manner



Actor portrayal.

This is not a guarantee of payment, coverage, or reimbursement. Alkermes does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding 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. Coding, 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

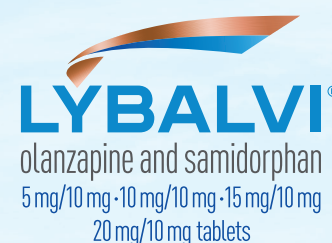
### Anticholinergic (Antimuscarinic) Effects:

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.

**Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full Prescribing Information, including Boxed Warning.**





### Will my patients need a prior authorization for LYBALVI®?

Once LYBALVI has been prescribed for your appropriate patients, a prior authorization may be required by some insurance plans. In some cases, a letter of medical necessity may be needed for LYBALVI to be covered. LYBALVI Care Support Administered by ASPN Pharmacies conducts benefits verification and can provide education and coordination in the prior authorization process. For more information about LYBALVI Care Support, see the LYBALVI Care Support tab of this guide, and for tips about the prior authorization and appeal processes, see the Prior Authorization & Appeals Reminders tab.

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

For tips about the prior authorization and appeal processes, see the Prior Authorization & Appeals Reminders tab of this guide. LYBALVI Care Support offers prior authorization education and coordination. Select ASPN Pharmacies within your EHR while prescribing LYBALVI or call **1-844-LYBALVI** (1-844-592-2584) for more information.

### 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 LYBALVI Care Support can help you with the appeal process. 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. For tips about the prior authorization and appeal processes, see the Prior Authorization & Appeals Reminders tab of this guide. A checklist for a letter of medical necessity or letter of appeal is also available at [LYBALVIaccess.com](https://lybalviaccess.com), which you can access by scanning the QR code to the right.



## Important Safety Information

### 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.

### Interference with Laboratory Tests for Opioid Detection:

LYBALVI may cause false positive results with urinary immunoassay methods for detecting opioids. Use an alternative analytical technique (e.g., chromatographic methods) to confirm positive opioid urine drug screen results.

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## FAQs (continued)

### Do Medicare and Medicaid cover LYBALVI®?

Medicare coverage for LYBALVI may vary among Medicare plans, while Medicaid coverage for LYBALVI may vary by state. Patients with Medicare should contact the Medicare benefits administrator, insurer, or plan provider. Medicaid patients can find information from their state Medicaid agency.

A full benefits verification is available through LYBALVI Care Support Administered by ASPN Pharmacies.

To request services, please select ASPN Pharmacies within your EHR while prescribing LYBALVI or call **1-844-LYBALVI** (1-844-592-2584) for more information.

### I have patients who do not have any insurance and can't afford LYBALVI. What are their options?

Alkermes is committed to helping appropriate patients gain access to LYBALVI when prescribed by a physician. For patients who do not have insurance, visit [LYBALVIhcp.com](https://LYBALVIhcp.com) and download the [LYBALVI Patient Assistance Program Enrollment Form](#) to apply.

- Patient must provide proof of household size and annual gross income and certify that they meet applicable financial and insurance criteria
- LYBALVI must be prescribed by a licensed US healthcare provider and be delivered to a location within the 50 states (excluding Puerto Rico and other US territories)
- Patient must be prescribed LYBALVI for an on-label use and be 18 years of age or older

LYBALVI Care Support can provide information about the Patient Assistance Program. You can call **1-844-LYBALVI** (1-844-592-2584), Monday through Friday, 9 AM to 8 PM ET.

## Important Safety Information

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

Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full [Prescribing Information](#), including Boxed Warning.





# FAQs (continued)

## What will my patient's co-pay be 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, 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. Health plan requirements for a prior authorization and/or step therapies must be attempted, and outcome documented, regardless of outcome, prior to using the co-pay benefit.

Over 90% of commercial patients utilizing the LYBALVI Co-pay Savings Program Card pay \$20 or less 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 should contact their state Medicaid agency to confirm the co-pay for LYBALVI.

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

Your Alkermes Representative can provide your practice with LYBALVI Co-pay Savings Program brochures, which include the Co-pay Savings Program Card, to give to your patients. No activation is required for the co-pay card inside the brochure. Patients may also download the card from [LYBALVICopay.com](https://LYBALVICopay.com) or by texting "COPAY" to 45286.

Patient prescriptions managed through LYBALVI Care Support will offer eligible patients the option to participate in the LYBALVI Co-pay Savings Program.

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

The LYBALVI® Co-pay Savings Program ("Program") is only available to commercially insured patients who are 18 years or older with a valid LYBALVI prescription. Health plan requirements for a prior authorization and/or step therapies must be attempted, and an outcome documented, regardless of the outcome, prior to using this co-pay offer. **This Program is not available to patients who are enrolled in Medicare, Medicaid, or other federal or state healthcare programs.** Maximum savings limit applies; patients' out-of-pocket expenses may vary. Maximum 30-day supply per fill for the first 3 fills in the Program. Beginning at fill 4 and thereafter, a maximum savings of \$450 per 30-day supply will be provided towards the cost of the LYBALVI prescription. **Please see full terms and conditions at [www.LYBALVI.com/copayterms](https://www.LYBALVI.com/copayterms). 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 ET, Monday-Friday).**

\*Based on out-of-pocket costs for commercially insured patients in the LYBALVI Co-pay Savings Program from April 2023 to June 2023.

## Important Safety Information

### 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.

**Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full Prescribing Information, including Boxed Warning.**



**LYBALVI®**  
olanzapine and samidorphan  
5 mg/10 mg - 10 mg/10 mg - 15 mg/10 mg  
20 mg/10 mg tablets

## FAQs (continued)

### Do my commercially insured patients need to enroll in LYBALVI® Care Support Administered by ASPN Pharmacies to use the LYBALVI Co-pay Savings Program?

Patients do not need to enroll in LYBALVI Care Support to use the Co-pay Savings Program. Patients may enroll online at [LYBALVICopay.com](https://LYBALVICopay.com) or by texting "COPAY" to 45286.

### How do I send a LYBALVI prescription to ASPN Pharmacies?

Within your EHR, search for "ASPN Pharmacies" or search by ASPN Pharmacies' ZIP Code (07039), state (New Jersey), NPI (1538590690), or NCPDP (3147863).

You can also send a prescription to ASPN Pharmacies via phone by calling **1-844-LYBALVI** (1-844-592-2584) or via fax to **1-877-FAX-LYBV** (1-877-329-5928), Monday through Friday, 9 AM to 8 PM ET.

To learn more about LYBALVI, visit [LYBALVIhcp.com](https://LYBALVIhcp.com)

For additional resources, contact your Alkermes Representative



## Important Safety Information

### 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<sup>2</sup>).

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

Please see additional Important Safety Information throughout the brochure and on pages 18-19 and full Prescribing Information, including Boxed Warning.

  
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olanzapine and samidorphan  
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20 mg/10 mg tablets



## 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.**

### 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.

### Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis,

including stroke, transient ischemia attack, and fatalities. See Boxed Warning.

### 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.

### Neuroleptic Malignant Syndrome,

a potentially fatal reaction. Signs and symptoms include hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatine 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.

(continued)



## Important Safety Information (continued)

### 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.

### Potential for Cognitive and Motor Impairment:

Because LYBALVI may cause somnolence, and may 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.

## Interference with Laboratory Tests for Opioid Detection:

LYBALVI may cause false positive results with urinary immunoassay methods for detecting opioids. Use an alternative analytical technique (e.g., chromatographic methods) to confirm positive opioid urine drug screen results.

## Most Common Adverse Reactions

observed in clinical trials were:

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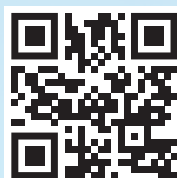


# LYBALVI® Care Support Administered by ASPN Pharmacies can help your office and your patients

For dedicated support throughout the prescription journey  
Call **1-844-LYBALVI** (1-844-592-2584), Monday through Friday, 9 AM to 8 PM ET

## TO LEARN MORE

About the LYBALVI Co-pay Savings Program, visit [lybalvihcp.com/patient-support/lybalvi-care](https://lybalvihcp.com/patient-support/lybalvi-care)



About LYBALVI, visit [LYBALVIhcp.com](https://LYBALVIhcp.com)



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