LYBALVI® Patient Assistance Program Enrollment Form

Complete all fields to avoid processing delays.
Fax completed form to: 1-877-FAX-LYBV (1-877-329-5928).
Questions? Call 1-844-LYBALVI (1-844-592-2584), 9 AM–8 PM (ET).

LYBALVI® olanzapine and samidorphan CARE SUPPORT

Prescriber Signature(s) (page 1) and Patient Signature(s) (page 2) required.

1. PRESCRIBER OR FACILITY INFORMATION

Prescriber
(First) (Last)

Tax ID # State License #

NPI # PTAN #

Facility Name

Facility Phone # Fax #

Address

City State ZIP Code

Staff Contact Name

Staff Contact Phone #

Staff Contact Email

2. PATIENT INFORMATION

Name
(First) (Middle Initial) (Last)

Date of Birth Last 4 digits SSN

Gender ☐ Male ☐ Female ☐ _____

Address

City State ZIP Code

Home Phone # Mobile Phone #

Phone Instructions (Best Number)

Email Address

→ *INSTRUCT PATIENT OF THE OPTION TO LIST ALTERNATE CONTACT ON PAGE 3*

3. PATIENT DIAGNOSIS
(A list of codes can be found on page 3, section 9)

Please check diagnosis

☐ Schizophrenia OR ☐ Bipolar I Disorder

ICD-10	ICD-10
F20. _____	F31. _____
F20. _____	F31. _____
F20. _____	F31. _____
F20. _____	F31. _____
F20. _____	F31. _____

Patient has tried and failed the following medication(s):

Please list any known allergies to medications or other substances:

Patient's concurrent medications:

4. PRESCRIPTION INFORMATION

Patient Name
(Required - Please Print Full Name)

LYBALVI® ☐ 5mg/10mg ☐ 10mg/10mg ☐ 15mg/10mg ☐ 20mg/10mg QTY: 30-Day Supply

Directions: 1 tablet by mouth daily. Refills

Provider State License #

By signing below, I certify that the therapy above is medically necessary. I authorize Alkermes, its affiliates, representatives and agents as my designated agents to forward the prescription, by fax or other mode of delivery, to a pharmacy for fulfillment.

Dispense as Written _____ Date _____
Prescriber Signature†

OR

Substitution Permitted _____ Date _____
Prescriber Signature†

†Prescriber Signature must be the same as the Prescriber Name. No Stamps allowed.

5. PRESCRIBER ATTESTATION

By signing below, I verify that the information provided in this LYBALVI Patient Assistance Program Enrollment Form is complete and accurate to the best of my knowledge. I understand that Alkermes, Inc., reserves the right at any time and for any reason, without notice, to modify this LYBALVI Patient Assistance Program Enrollment Form or to modify or discontinue any services or assistance provided through LYBALVI Patient Assistance Program. I authorize Alkermes, its affiliates, representatives and agents as my designated agents to use and disclose my patient's health information as necessary to verify the accuracy of any information provided and to provide the LYBALVI Patient Assistance Program services requested.

I authorize UBC to use the Surescripts network on my behalf to verify patient's health insurance information for participation in this program. Alkermes will notify me if the information provided by Surescripts to UBC on behalf of me renders the patient ineligible for this program. I agree to comply with all Surescripts terms and conditions including confidentiality, privacy and security, applicable laws, and use of data with respect to any information provided to me that was obtained by UBC from Surescripts, on behalf of me. All Surescripts disclaimers apply. A full list of terms and conditions is available at https://ubc.com/surescriptsterms.

☐ **I certify I have investigated alternative funding sources administered by federal, state and local governments, prior to applying for the Patient Assistance Program.**

Prescriber Signature† X _____ Date _____

†Prescriber Signature must be the same as the Prescriber Name. No Stamps allowed.

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6. PATIENT ASSISTANCE PROGRAM For Patient Assistance Program Only

☐ Check here if you would like to be assessed for the Patient Assistance Program. I am a US Resident. ☐ Yes ☐ No

FINANCIAL INFORMATION (ALL VALUES SHOULD REFLECT YEARLY AMOUNTS FOR ENTIRE HOUSEHOLD)

Total Gross Yearly Income: _____

Household Size: _____
(Number of people who contribute to or are dependent on your household income.)

Please check what best applies:

- ☐ 3 recent pay stubs
- ☐ 3 months of recent bank statements
- ☐ Most recent W-2
- ☐ Most recent federal tax return (1040)
- ☐ SSI proof of income letter
- ☐ Unemployment benefit letter (dollar amount included)

OR:

- ☐ I do not file federal taxes (Additional follow-up or documentation may be required for patients who do not file taxes)

Please check all boxes below to indicate that you understand and agree to the following:

☐ I understand that to qualify for the Patient Assistance Program, my household income and household size must meet program requirements. I certify that my household size and household income, provided above, are accurate, as is my income documentation. I certify that the health insurance information or selection of "Uninsured" in Section 5 (page 1) is accurate. I understand that my eligibility will be based on additional program requirements and, if approved, I must continue to meet eligibility requirements on an ongoing basis as defined by the program in order to receive benefits. I certify that I will notify the Patient Assistance Program at 1-888-592-2584 if my income or health insurance status changes in order to reassess my eligibility. I understand that if I am no longer eligible I will be removed from the program. Subject to continuing eligibility, patients will be approved for 12 months for a maximum of 12 dispenses of the prescription. Patients requiring assistance beyond 12 months will be required to reapply for continued program eligibility.

☐ I am not 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 or Medicaid, Medigap, VA, DOD, TRICARE or a residential correctional program).

☐ I understand that Alkermes, Inc. and the vendors associated with the PAP may obtain information about my credit profile from credit reporting agencies or other sources. I authorize this credit report to determine my PAP eligibility, and I acknowledge that this authorization extends to consumer reporting agencies and to subsequent reports in connection with PAP.

☐ **I am unaware of or do not have access to alternative sources of coverage or funding.**
Your application may be subject to audit or request for additional documentation.

Patient's Signature X _____ Date _____

–or–

Guardian/Legal Representative's Signature‡ X _____ Guardian's Printed Name _____ Date _____ Authority/ Relationship to Patient _____

‡If patient does not have capacity to act alone under state law, signature of guardian or authorized legal representative is required.

7. PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION (Required)

By signing below, I authorize my "Healthcare Providers" (eg, my physicians, pharmacists, pharmacies, other healthcare providers, and their staff) and my "Insurers" to share information about me as detailed in this Enrollment Form (my "Personal Information"). My "Personal Information" includes any and all information related to my health, including my diagnosis and treatment. My Personal Information also includes my identifying information, contact's information, my health insurance information, financial information relevant to my eligibility for LYBALVI Care Support Program services, and all other information described on this Enrollment Form.

I authorize my Healthcare Providers and Insurers to share my Personal Information with Alkermes, Inc., its affiliated companies, agents, and service providers for the LYBALVI Care Support Program (collectively, "Alkermes") so they may provide the services described below (the "Services").

I authorize Alkermes to use and share my Personal Information with my Healthcare Providers, Insurers, and Designated Contact(s) to perform the Services, including: 1. Ordering and delivering LYBALVI (the "Product"); 2. conducting reimbursement verification and obtaining payment from my Insurer; 3. providing me with educational and therapy support services by using my provided contact information to communicate with me by mail, text message, e-mail, and/or telephone, which may include treatment reminders, information about the LYBALVI Care Support Program or the LYBALVI Co-pay Savings Program, and motivational messages; 4. referring me to, or determining my eligibility for, other programs, foundations or alternative sources of funding or coverage to help me with the costs of the Product(s); 5. helping with my enrollment and continued participation in the LYBALVI Co-pay Savings

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7. PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION, CONTINUED (Required)

Program in the event I am eligible for such program; and 6. conducting analysis to help Alkermes evaluate, create, and improve products and services for patients prescribed Alkermes medications.

I understand that once Personal Information is disclosed pursuant to this authorization, some of the information may not be regulated by applicable privacy regulations and could be re-disclosed, but I also understand that Alkermes does not intend to make any disclosures other than as described in this authorization. I understand that my pharmacy may receive remuneration in exchange for the use or disclosure of my Personal Information and/or any patient support services provided to me.

I understand I have the right to receive a copy of this authorization after I sign. I understand that signing this authorization is voluntary, and that if I do not sign this consent, it will not affect my ability to obtain treatment, insurance or insurance benefits. I understand, however, that if I do not sign this consent, I will not be eligible to receive the financial, educational, or other services provided by the LYBALVI Care Support Program.

I may withdraw this authorization at any time by mailing or faxing a written request to LYBALVI Care Support, 900 Winter Street, Waltham, MA 02451, 1-877-329-5928. Withdrawal of this authorization will not, however, invalidate disclosures and uses of my Personal Information prior to the date my notice of withdrawal is received by Alkermes.

This consent expires five (5) years from the date of my signature below unless an earlier expiration is mandatory under applicable state law.

For additional information about our privacy practices, please visit https://www.Alkermes.com/privacy-policy.

Patient's Signature X _____ Date _____

–or–

Guardian/Legal Representative's Signature‡ X _____ Guardian's Printed Name _____ Date _____ Authority/ Relationship to Patient _____

‡If patient does not have capacity to act alone under state law, signature of guardian or authorized legal representative is required.

8. ALTERNATE PATIENT CONTACT(S) *(OPTIONAL)*

By signing below, I authorize my Contact(s), listed below, to receive logistical and administrative information related to my treatment and to make decisions on my behalf—for which I will remain liable—regarding delivery of LYBALVI. Alkermes is not liable for any decision(s) made by the Contact(s) or actions taken in reliance on such Contact(s) decisions.

Please list any Contacts authorized as set forth above:

Designee Name (1) _____ Relationship _____ Phone # _____ ☐ Home ☐ Mobile ☐ Work

Designee Name (2) _____ Relationship _____ Phone # _____ ☐ Home ☐ Mobile ☐ Work

Patient's Signature X _____ Date _____

–or–

Guardian/Legal Representative's Signature‡ X _____ Guardian's Printed Name _____ Date _____ Authority/ Relationship to Patient _____

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9. PATIENT DIAGNOSIS CODES

Schizophrenia

(ICD-10-CM)

F20.0	Paranoid schizophrenia
F20.1	Disorganized schizophrenia
F20.2	Catatonic schizophrenia
F20.3	Undifferentiated schizophrenia
F20.5	Residual schizophrenia
F20.89	Other schizophrenia
F20.9	Schizophrenia, unspecified

Bipolar I Disorder

(ICD-10-CM)

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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 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.

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.

(CONTINUED)

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IMPORTANT SAFETY INFORMATION *(Continued)*

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.

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:

- *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

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.

PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR LYBALVI.