Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Olanzapine and Samidorphan (Lybalvi)

Notes:

- ^Adequate trial defined as 2 week period without clinically significant improvement in target symptoms or side effects related to dosage form that cannot be resolved by adjusting dose or timing.
- *Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation.

<u>Initiation (new start) criteria</u>: Nonformulary olanzapine and samidorphan (Lybalvi) will be covered on the prescription drug benefit when the following criteria are met:

Schizophrenia:

- Diagnosis of schizophrenia
- Patient is 18 years of age or older
- Patient has a BMI ≥ 30 kg/m² or has diagnosis of diabetes mellitus -OR- patient has failed a trial^ of olanzapine or patient has an allergy or intolerance* to inactive ingredients in all available generic forms of olanzapine
- Patient has failed an adequate trial of 2 other formulary antipsychotic agents (e.g., quetiapine, risperidone, olanzapine, aripiprazole, ziprasidone, clozapine or first-generation antipsychotic)

Bipolar Disorder

- Prescriber is a mental health clinician
- Diagnosis of bipolar disorder
- Patient is 18 years of age or older
- Patient has a BMI ≥ 30 kg/m² or has diagnosis of diabetes mellitus -OR- patient has failed an adequate trial^ of olanzapine or patient has an allergy or intolerance* to inactive ingredients in all available generic forms of olanzapine
- Patient has failed an adequate trial[^] of 2 other formulary antipsychotic agents (e.g., quetiapine, risperidone, olanzapine, aripiprazole, ziprasidone, clozapine or firstgeneration antipsychotic) or mood stabilizers (lithium, valproate, lamotrigine, carbamazepine, etc.)

kp.org

Revised: 01/13/22 Effective: 03/03/22 All plans offered and underwritten by Kaiser Foundation Health Plan of the Northwest



Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Olanzapine and Samidorphan (Lybalvi)

<u>Criteria for members already taking the medication who have not been reviewed</u> <u>previously (e.g., new members)</u>: Nonformulary olanzapine and samidorphan (Lybalvi) will be covered on the prescription drug benefit when the following criteria are met:

Schizophrenia:

- Diagnosis of schizophrenia
- Patient is 18 years of age or older
- Patient has a BMI ≥ 30 kg/m² or has diagnosis of diabetes mellitus

-OR-

 Patient has failed an adequate trial[^] of olanzapine or patient has an allergy or intolerance^{*} to inactive ingredients in all available generic forms of olanzapine

Bipolar Disorder

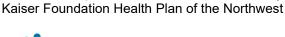
- Diagnosis of bipolar disorder
- Patient is 18 years of age or older
- Patient has a BMI ≥ 30 kg/m² or has diagnosis of diabetes mellitus

-OR-

 Patient has failed an adequate trial[^] of olanzapine or patient has an allergy or intolerance^{*} to inactive ingredients in all available generic forms of olanzapine

kp.org

Revised: 01/13/22 Effective: 03/03/22





All plans offered and underwritten by