Effective Date: 06/01/2022
Reviewed: 03/2022, 3/2023 Scope: Medicaid

Lybalvi (olanzapine and samidorphan l-malate)

POLICY

I. CRITERIA FOR APPROVAL

An authorization of 6 months may be granted when all the following criteria are met:

A. The patient is 18 years of age or older.
B. The patient has documented diagnosis of Schizophrenia or Bipolar I Disorder.
C. Patient does not have a known opioid use disorder or is not utilizing opioids for a chronic health condition.
D. The patient has a documented inadequate treatment response to the following:
    a. The patient experienced an inadequate treatment response after a trial of at least 30 days, or intolerance to three preferred oral generic atypical antipsychotics at maximally tolerated doses; OR
    b. Trial of generic olanzapine for less than 6 months with documentation demonstrating positive therapeutic benefit but unacceptable weight gain (i.e., 7% increase from baseline) while on therapy.
E. A baseline metabolic panel has been documented (including glucose, lipid, and patient's baseline weight) and will continue to be monitored throughout therapy.

II. CONTINUATION OF THERAPY

An authorization of 12 months may be granted when all the following criteria are met:
A. The patient is tolerating treatment with Lybalvi
B. The patient's metabolic panel has been documented (including glucose, lipid, and patient's current weight) since baseline and has been reviewed within the last 3 months
C. The patient has experienced a positive clinical response to therapy and has not had any adverse effects (i.e., severe metabolic changes, weight gain (i.e., less than 4% from baseline), tardive dyskinesia, etc.)
D. Patient has not had more than a 4.2% weight gain over baseline start weight.

III. QUANTITY LIMIT

Lybalvi 5mg/10mg, 10mg/10mg, 15mg/10mg, 20mg/10mg: one tablet per day

IV. REFERENCES

Lybalvi [package insert]. Waltham, MA: Alkermes, Inc.; February 2022.