Clinical Policy: Olanzapine/Samidorphan (Lybalvi)

Reference Number: IN.CP.PMN.265
Effective Date: 01.01.2022
Last Review Date: 12.21
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Olanzapine/samidorphan (Lybalvi™) is combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist.

FDA Approved Indication(s)

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Prescription claim should reject if an opiate claim is found in the past 60 days.:

I. Initial Approval Criteria

1. **Deny if member meets any of the following criteria (May use prescription claim history as well as INSPECT to validate).**
   a. Use of opiate agonists (including buprenorphine) concurrently with olanzapine/samidorphan
   b. Use of short-acting opiate agonists less than or equal to 7 days prior to initiating olanzapine/samidorphan therapy
   c. Use of long-acting opiate agonists less than or equal to 14 days prior to initiating olanzapine/samidorphan therapy
2. ; Member must be over 18 years old
3. ;Quality limits:
   a. Lybalvi 5-10mg 1 per day
   b. Lybalvi 10-10mg 1 per day
   c. Lybalvi 15-10mg 1 per day
   d. Lybalvi 20-20mg 1 per day

Approval duration: Enter a 1 time override for next 60 days.

II. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMI: body mass index
FDA: Food and Drug Administration

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): patients using opioids, patients undergoing acute opioid withdrawal
- Boxed warning(s): increased mortality in elderly patients with dementia-related psychosis

III. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia	Initiate at 5 mg/10 mg or 10 mg/10 mg PO QD. The recommended dosage is 10 mg/10 mg, 15 mg/10 mg, or 20 mg/10 mg. Dosage may be adjusted at weekly intervals of 5 mg (based on the olanzapine component) depending upon clinical response and tolerability.	20 mg/10 mg/day
Bipolar I disorder	Monotherapy: Initiate at 10 mg/10 mg or 15 mg/10 mg PO QD. The recommended dosage is 10 mg/10 mg, 15 mg/10 mg, or 20 mg/10 mg PO QD. Dosage adjustments should occur at intervals of not less than 24 hours. When dosage adjustments are necessary, dose increments/decrements of 5 mg (based on the olanzapine component) are recommended. Maintenance monotherapy: Administer at 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, or 20 mg/10 mg PO QD. Adjunctive to lithium or valproate: Initiate at 10 mg/10 mg PO QD. The recommended dosage is 10 mg/10 mg, 15 mg/10 mg or 20 mg/10 mg PO QD. Dosage may be adjusted at weekly intervals of 5 mg (based on the olanzapine component), depending upon clinical response and tolerability.	20 mg/10 mg/day

IV. Product Availability

Tablets (olanzapine/samidorphan): 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, 20 mg/10 mg

V. References

1. Lybalvi Prescribing Information. Waltham, MA: Alkermes, Inc.; May 2021. Available at: http://www.lybalvi.com. Accessed June 3, 2021.
2. Keepers G, Fochtmann L, Anzia J, et al. American Psychiatric Association practice guideline for the treatment of patients with schizophrenia, third edition (2020). Available at: https://psychiatryonline.org/doi/10.1176/appi.books.9780890424841. Accessed June 4, 2021.
3. McDonagh MS, Dana T, Selph S, Devine EB, et al. Treatments for schizophrenia in adults: A systematic review. Comparative Effectiveness Review No. 198. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 17(18)-EHC031-EF. Rockville, MD: Agency for Healthcare Research and Quality; October 2017. DOI: https://doi.org/10.23970/AHRQEPCCER198.
4. Hirschfield RMA, Bowden CL, Gitlin MJ, et al. American Psychiatric Association practice guideline for the treatment of patients with bipolar disorder, second edition (2010). Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf . Accessed June 4, 2021.
5. Butler M, Urosevic S, Desai P, et al. Treatment for bipolar disorder in adults: A systematic review. Comparative Effectiveness Review No. 208. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2012-00016-I.) AHRQ Publication No. 18-EHC012-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2018. DOI: https://doi.org/10.23970/AHRQEPCCER208.
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 3, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.03.21	08.21
Policy created for IN Medicaid State Moratorium	12.21	01.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.