Clinical Policy Title:	olanzapine and samidorphan
Policy Number:	RxA.697
Drug(s) Applied:	Lybalvi™
Original Policy Date:	08/16/2021
Last Review Date:	12/1/2023
Line of Business Policy Applies to:	All line of business (except Medicare)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Schizophrenia and Bipolar Disorder (must meet all):

1. Diagnosis of bipolar disorder or schizophrenia;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with a psychiatrist;
4. Patient does not have a known opioid use disorder, undergoing acute opioid withdrawal or is dependent on opioids;
5. Trial and failure of generic olanzapine for at least 4 weeks with documentation demonstrating positive therapeutic benefit but clinically significant weight gain (at least 3%) while on therapy, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All the indication in Section I (must meet all):

1. Member is currently receiving medication, excluding manufacturer samples

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Keepers GA, et al. The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia, third edition. *Am J Psychiatry*. 2020;177(9):868-872. doi: 10.1176/appi.ajp.2020.177901. Available at: https://ajp.psychiatryonline.org/doi/10.1176/appi.ajp.2020.177901. Accessed April 22, 2022.
2. Kinon BJ, et al. Long-term olanzapine treatment: weight change and weight-related health factors in schizophrenia. *J* Clin Psychiatry. 2001;62(2):92-100. Available at: https://pubmed.ncbi.nlm.nih.gov/11247108/. Accessed April 22, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	08/16/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A: Updated to include indication Bipolar Disorder. 2. Initial Approval Criteria, I.A.1: Updated indication from Diagnosis of schizophrenia to Diagnosis of bipolar disorder or schizophrenia. 3. Initial Approval Criteria, I.A.4: Updated to remove prior diagnostic criteria "Member meets DSM 5 criteria for schizophrenia". 4. Initial Approval Criteria, I.B: Updated to remove approval criteria for Bipolar I Disorder. 5. Appendix A: Updated to include abbreviation NMS. 6. Appendix B, Drug Name: Updated to include new therapeutic alternative a. risperidone (Risperdal®) b. aripiprazole (Abilify®) c. quetiapine (Seroquel®) d. olanzapine (Zyprexa®) e. ziprasidone (Geodon®) 7. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 8. References were reviewed and updated.	4/22/2022	07/18/2022
Policy was reviewed.	12/1/2023	12/1/2023