

Clinical Policy Title:	olanzapine and samidorphan
Policy Number:	RxA.884
Drug(s) Applied:	Lybalvi
Original Policy Date:	04/10/2025
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Schizophrenia or Bipolar I Disorder (must meet all):

1. Diagnosis of schizophrenia or bipolar I disorder;
2. Trial and failure for at least 8 weeks total of all the following, unless contraindicated or clinically adverse effects are experienced (i, ii, and iii):
 - i. Olanzapine;
 - ii. Two generic atypical antipsychotics (quetiapine, risperidone, aripiprazole, lurasidone, paliperidone, or ziprasidone);
 - iii. Vraylar.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Schizophrenia or Bipolar I Disorder (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for members responding positively to therapy with RxAdvance initial approval.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. PI: [label](#)

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	4/10/25	4/10/25
Policy reviewed 1. Rexulti removed	2/13/2026	NA

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.