



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLANZAPINE/SAMIDORPHAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLANZAPINE/ SAMIDORPHAN MALATE	LYBALVI	47406		GPI-10 (6299480250)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?

- The patient has a diagnosis of schizophrenia
- The patient has a diagnosis of bipolar I disorder and meets ONE of the following:
 - Lybalvi is being used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
 - Lybalvi is being used as maintenance monotherapy treatment

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a psychiatrist
- The patient is at high risk for weight gain
- The patient had a trial and failure of or contraindication to BOTH of the following:
 - TWO generic antipsychotics (e.g., aripiprazole, quetiapine, risperidone, etc.)
 - ONE of the following preferred brand agents: Vraylar, Latuda or Rexulti

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Schizophrenia (type of mental health disorder)
2. Bipolar I disorder (type of mood disorder)

B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)

D. You are at high risk for weight gain

E. You had a trial and failure of or contraindication (harmful for) to BOTH of the following:

1. TWO generic antipsychotics (such as aripiprazole, quetiapine, risperidone)
2. ONE of the following preferred brand agents: Vraylar, Latuda or Rexulti

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

F. If you have bipolar I disorder, approval also requires ONE of the following:

1. Lybalvi is being used for acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate
2. Lybalvi is being used as maintenance monotherapy treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lybalvi.

REFERENCES

- Lybalvi [Prescribing Information]. Waltham, MA: Alkermes, Inc., May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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