UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2233-6
Program	Prior Authorization/Medical Necessity
Medication/Therapeutic Class	Lithobid® (brand only)
P&T Approval Date	3/2021, 3/2022, 3/2023, 11/2023, 7/2024, 9/2025
Effective Date	11/16/2025

1. Background:

This program requires a member to try an AB-rated generic lithium prior to receiving coverage for brand Lithobid.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Lithobid (brand only)** will be approved based on **one** of the following criteria:

   a. **Both** of the following:

      (1) History of greater than or equal to 4 week trial of generic lithium (document date of trial)

      -AND-

      (2) Documented history of an inadequate response to generic lithium (document inadequate response)

      -OR-

   b. History of an intolerance to generic lithium which was unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. change timing of dosing, divide daily dose out for more frequent but smaller doses, lowering dose)

      -OR-

   c. Currently established on Lithobid and stable.

Authorization will be issued for 12 months.

B. Reauthorization

1. **Lithobid (brand only)** will be approved based on the following criterion:

   a. Documentation of positive clinical response to therapy

Reauthorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Lithobid [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc; October 2022.
2. Gitlin, M. Lithium side effects and toxicity: prevalence and management strategies. Int J Bipolar Disord. 2016;4(1):27. Epub 2016 Dec 17.

Program	Prior Authorization/Medical Necessity – Lithobid (brand only)
Change Control	
Date	Change
3/2021	New program.
3/2022	Annual review. No changes.
3/2023	Annual review. Updated references.
11/2023	No changes.
7/2024	Removed therapeutic levels requirement for generic trial and stability duration.
9/2025	Annual review. No changes.