UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1314-5
Program	Prior Authorization/Notification
Medication	Caplyta® (lumateperone)
P&T Approval Date	5/2020, 8/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Caplyta is FDA approved for the treatment of schizophrenia and for depressive episodes associated with bipolar I or II disorder as monotherapy and as adjunctive therapy with lithium or valproate in adults. Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Initial Authorization

a. **Caplyta** will be approved based on **one** of the following criteria:

(1) Diagnosis of schizophrenia

(2) Diagnosis of depressive episodes associated with bipolar I or II disorder (bipolar depression)

Authorization will be issued for 12 months.

B. Reauthorization

a. **Caplyta** will be approved for continuation of therapy based on the following criterion:

(1) Documentation of a positive clinical response to therapy

Authorization 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 Rules:

- 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.
- Step Therapy and Supply limits may be in place.

4. References:

1. Caplyta [package insert]. New York, NY: Intra-Cellular Therapies, Inc. June 2023.

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Change Control	
5/2020	New program.
8/2021	No changes.
3/2022	Updated to include coverage for depressive episodes associated with bipolar disorder due to new labeling.
3/2023	Annual review. Updated reference. Added state mandate language.
3/2024	Annual review. Updated reference.