



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3138-5
Program	Step Therapy
Medication	Caplyta® (lumateperone)
P&T Approval Date	5/2020, 6/2021, 6/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. 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.

This program requires a member to try three atypical antipsychotics for schizophrenia or two atypical antipsychotics for bipolar depression before providing coverage for Caplyta.

2. Coverage Criteria^a:

A. Initial Authorization for Depressive Episodes Associated with Bipolar Disorder

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

a. History of failure, contraindication, or intolerance to **both** of the following (please document date and duration of trial):

- (1) olanzapine (generic Zyprexa) in combination with an SSRI (e.g. fluoxetine)
- (2) quetiapine IR or ER (generic Seroquel or Seroquel XR)

-OR-

2. Treatment with Caplyta was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

-OR-

3. Member is new to the plan and currently stabilized on Caplyta (as evidenced by coverage effective date of less than or equal to 120 days)

Authorization will be issued for 12 months.

B. Initial Authorization for Schizophrenia and All Other Indications

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

- a. History of failure, contraindication, or intolerance to **three** of the following (please document drug, date and duration of trial):

- (1) aripiprazole (generic Abilify)
- (2) olanzapine (generic Zyprexa)
- (3) quetiapine IR or ER (generic Seroquel or Seroquel XR)
- (4) risperidone (generic Risperdal)
- (5) ziprasidone (generic Geodon)

-OR-

2. Treatment with Caplyta was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

-OR-

3. Member is new to the plan and currently stabilized on Caplyta (as evidenced by coverage effective date of less than or equal to 120 days)

Authorization will be issued for 12 months.

C. Reauthorization

1. **Caplyta** 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.
- Supply limits and Prior Authorization/Notification may also be in place.

4. References:

1. Caplyta [package insert]. New York, NY: Intra-Cellular Therapies, Inc. June 2023.
2. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia Third Edition. Available at:

http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf

3. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Bipolar Disorder Second Edition. Available at:
https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf

Program	Step Therapy - Caplyta (lumateperone)
Change Control	
5/2020	New program.
6/2021	Annual review. Added continuation of therapy coverage criteria. Updated references.
6/2022	Annual review. Added criteria for the new indication for depressive episodes associated with bipolar disorder. Updated references.
11/2023	Updated references.
11/2024	Annual review with no changes.