UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2208-8
Program	Prior Authorization/Medical Necessity
Medication	Caplyta® (lumateperone)
P&T Approval Date	6/2020, 7/2021, 3/2022, 6/2022, 11/2023, 11/2024, 11/2025, 1/2026
Effective Date	4/1/2026

1. Background:

Caplyta is FDA approved for the treatment of schizophrenia, for depressive episodes associated with bipolar I or II disorder as monotherapy and as adjunctive therapy with lithium or valproate and for the adjunctive therapy with antidepressants for the treatment of major depressive disorder 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

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

   a. **BOTH** of the following:

      1) Diagnosis of schizophrenia

      -AND-

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

         (a) aripiprazole (generic Abilify)
         (b) lurasidone (generic Latuda)
         (c) olanzapine (generic Zyprexa)
         (d) quetiapine IR or ER (generic Seroquel or Seroquel XR)
         (e) risperidone (generic Risperdal)
         (f) ziprasidone (generic Geodon)

      -OR-

   b. **BOTH** of the following:

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

      -AND-

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

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

-OR-

c. **ALL** of the following:

1) Diagnosis of major depressive disorder (MDD)

-AND-

2) Caplyta is being used in combination with an antidepressant medication

-AND-

3) The patient has a history of failure, contraindication or intolerance to a trial of at least one selective serotonin reuptake inhibitor (SSRI). (Document drug, date and duration of trial).

-AND-

4) The patient has a history of failure, contraindication or intolerance to a trial of at least one serotonin norepinephrine reuptake inhibitor (SNRI), mirtazapine, or bupropion. (Document drug, date and duration of trial).

-AND-

5) The patient has a history of failure, contraindication or intolerance to a trial of at least **one** of the following atypical antipsychotics approved by the FDA for the adjunctive treatment of major depressive disorder with an antidepressant (Document drug, date and duration of trial):

(a) aripiprazole
(b) olanzapine
(c) quetiapine extended-release

-OR-

d. 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-

e. 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. <u>Reauthorization</u>

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

a. 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 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]. Bedminster, NJ: Intra-Cellular Therapies, Inc. November 2025.
2. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia Third Edition. Available at: https://psychiatryonline.org/doi/10.1176/appi.books.9780890424841
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	Prior Authorization/Medical Necessity - Caplyta (lumateperone)
Change Control	
6/2020	New program.
7/2021	Annual review. Updated references and added continuation of therapy coverage criteria.
3/2022	Updated to include coverage for depressive episodes associated with bipolar disorder due to new labeling.
6/2022	Modified criteria for bipolar depression. Updated references.
11/2023	Updated references.
11/2024	Annual review with no changes.
11/2025	Annual review with no changes.

1/2026	Added lurasidone to step one options for schizophrenia. Added requirements for new indication of major depressive disorder.