UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 2208-6 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Caplyta® (lumateperone) |
| P&T Approval Date | 6/2020, 7/2021, 3/2022, 6/2022, 11/2023, 11/2024 |
| Effective Date | 2/1/2025 |

**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. 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) olanzapine (generic Zyprexa)
         (c) quetiapine IR or ER (generic Seroquel or Seroquel XR)
         (d) risperidone (generic Risperdal)
         (e) 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. 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-**

d. 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. Reauthorization**

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]. 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: 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. |