



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3138-1
Program	Step Therapy
Medication	Caplyta (lumateperone)
P&T Approval Date	5/2020
Effective Date	7/1/2020; Oxford only: 7/1/2020

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 in adults.

This program requires a member to try three atypical antipsychotics before providing coverage for Caplyta.

2. Coverage Criteria^a:

A. Initial Authorization

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
- (2) olanzapine
- (3) quetiapine IR or ER
- (4) risperidone
- (5) ziprasidone

-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).

Authorization will be issued for 12 months.

B. 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 [prescribing information]. New York, NY: Intra-Cellular Therapies, Inc. December 2019.
2. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia Second Edition. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia.pdf

Program	Step Therapy - Caplyta (lumateperone)
Change Control	
5/2020	New program.