Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 29, 2021 December 22, 2021, May 19, 2022

CAPLYTA® (lumateperone)

LENGTH OF AUTHORIZATION: Up to one year

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- **For the treatment of schizophrenia**, patient must have a history, within the past 365 days of trial and failure of a preferred atypical antipsychotic with a minimum 30-day treatment period.
- **For the treatment of depressive episodes associated with bipolar I or II disorder as monotherapy or as adjunctive therapy**, patient must have failed to respond or be intolerant to an adequate trial of at least two of the following:
  - Lithium; **OR**
  - Valproic Acid; **OR**
  - Combination of a mood stabilizer and one preferred atypical antipsychotic; **OR**
  - Combination of two or more mood stabilizers.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as: 42 mg, 21 mg and 10.5 mg capsule.
- Refer to product labeling https://www.accessdata.fda.gov/scripts/cder/daf/