



Commercial/Healthcare Exchange PA Criteria
Effective: April 10, 2020

Prior Authorization: Caplyta

Products Affected: Caplyta (lumateperone) oral capsule

Medication Description: Caplyta is an atypical antipsychotic agent but the exact mechanism of action is unknown. However, the mechanism could be through a combination of antagonist activity at central 5-HT_{2A} receptors and postsynaptic antagonist activity at central dopamine D₂ receptors.

Covered Uses:

1. Treatment of schizophrenia in adults.
2. Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy or as adjunctive therapy with lithium or valproate

Exclusion Criteria: Known hypersensitivity to lumateperone or any components of Caplyta

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed

Age Restrictions: 18 years of age and older

Prescriber Restrictions: N/A

Coverage Duration:

Initial approval: 3 months, Continuation: 1 year

Other Criteria:

1. Schizophrenia
Approve if patient meets the following criteria (A AND B)
 - A. Patient has a diagnosis of schizophrenia; AND
 - B. Patient has had a trial and failure, intolerance, or contraindication to AT LEAST TWO of the following:
 - i. Aripiprazole
 - ii. Clozapine
 - iii. Risperidone
 - iv. Quetiapine
 - v. Olanzapine
 - vi. Ziprasidone
2. Bipolar Depression - Bipolar I or II disorder
Approve if patient meets the following criteria (A AND B)
 - A. Patient has a diagnosis of depressive episodes associated with bipolar I or II disorder (bipolar depression) and meets ONE of the following (i OR ii)
 - i. Used as monotherapy OR

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- ii. Used as an adjunctive therapy with lithium or valproate
- B. Patient has had a trial and failure, intolerance, or contraindication to at least TWO of the following
 - i. Aripiprazole
 - ii. Risperidone
 - iii. Quetiapine
 - iv. Olanzapine plus fluoxetine
 - v. Ziprasidone

Continuation:

Patient achieves or maintains a positive response and is not experiencing toxicity from therapy.

References:

1. Caplyta[®] capsules [prescribing information]. New York, NY: Intra-Cellular Therapies, Inc.; December 2019.
2. Lieberman JA, Davis RE, Correll CU, et al. ITI-007 for the treatment of schizophrenia: a 4-week randomized, double-blind, controlled trial. *Biological Psychiatry*. 2016;79:952-961.
3. Correll CU, Davis RE, Weingart M, et al. Efficacy and safety of lumateperone for treatment of schizophrenia: a randomized clinical trial. *JAMA Psychiatry*. 2020 Jan 8. [Epub ahead of print].
4. Data on file. Caplyta[™] (lumateperone 42 mg capsules) Product Dossier: AMCP dossier, version 1.0. Intra-Cellular Therapies, Inc.; received January 13, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/6/2020
2	Update	Added indication for Depressive episodes associated with bipolar I or II disorder (bipolar depression) Added Known hypersensitivity to lumateperone or any components of Caplyta Added criteria for Bipolar Depression	Covered uses Exclusion Criteria Other Criteria	7/5/2022