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-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

Covered Uses: Treatment of schizophrenia in adults.

Exclusion Criteria: N/A

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:

A. Patient has a diagnosis of schizophrenia; AND
B. Patient has had a trial and failure, intolerance, or contraindication to AT LEAST TWO generic antipsychotics (aripiprazole, clozapine, risperidone, quetiapine, olanzapine, ziprasidone).

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