

## Caplyta (lumateperone)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Caplyta (lumateperone) is an atypical antipsychotic medication used in the treatment of schizophrenia in adults, as well as depressive episodes associated with bipolar I or II disorder in adults, both as a monotherapy and as adjunctive therapy with lithium or valproate.

Bipolar depression and schizophrenia are different types of mental health conditions. Treatment plans for both conditions usually include both drug and non-drug treatments. Medicines, such as Caplyta (lumateperone), are often a part of treatment for both bipolar depression and schizophrenia. Other medications in the group of second generation antipsychotics include, but are not limited to aripiprazole, olanzapine, quetiapine, risperidone, and ziprasidone. Tolerance and response to antipsychotic agents vary, and patients who do not tolerate or respond to a specific agent may be treated with a different agent and expect a different response or adverse effect(s). The choice of an antipsychotic agent depends on a multitude of factors, including but not limited to response (or lack thereof) to previously used medications, safety and tolerability of each agent, and patient-specific considerations.

## Definitions

“**Adjunctive therapy**” is treatment with an additional medication added to the main therapy.

“**Atypical antipsychotics**” are second generation antipsychotic medications used to treat conditions like schizophrenia and bipolar disorder. Examples include aripiprazole, olanzapine, quetiapine, risperidone, ziprasidone.

“**Bipolar depression**” refers to depressive episodes associated with bipolar disorder.

“**Bipolar disorder**” is a mental health condition characterized by extreme mood swings between manic and depressive episodes.

“**Monotherapy**” means treatment with a single medication.

“**Schizophrenia**” is a chronic mental health condition characterized by hallucinations, delusions, disorganized thinking and behavior.

“**Schizoaffective disorder (ScAD)**” is a mental health condition which has both psychotic symptoms and mood (affective) disorder symptoms. People with ScAD may have symptoms of depression (e.g., feeling sad, empty) or mania (e.g., raised mood, feel powerful and can do anything).

## Clinical Indications

### Medical Necessity Criteria for Initial Authorization

The Plan considers **Caplyta (lumateperone)** medically necessary when **ALL** of the following criteria are met:

1. The medication is prescribed by or in consultation with a psychiatrist; **AND**
2. The member is 18 years of age or older; **AND**
3. The member meets the applicable indication-specific criteria listed below:

#### **Bipolar Disorder:**

1. The medication is being requested for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression); **AND**
2. The member has tried and failed at least a one-month trial of **ONE** of the following:
  - a. Lurasidone; **and/or**
  - b. Quetiapine immediate-release or extended-release; **and/or**
  - c. Olanzapine and fluoxetine in combination.

### **Schizophrenia:**

1. The member has a diagnosis of schizophrenia; **AND**
2. The member is unable to use or has adequately tried and failed at least a one-month trial to **TWO** (2) of the following:
  - a. Aripiprazole; **and/or**
  - b. Olanzapine; **and/or**
  - c. Risperidone; **and/or**
  - d. Paliperidone; **and/or**
  - e. Quetiapine; **and/or**
  - f. Ziprasidone.

### **Schizoaffective Disorder:**

1. The member has a diagnosis of schizoaffective disorder; **AND**
2. The member is unable to use or has adequately tried and failed at least a one-month trial to **BOTH** of the following:
  - a. Paliperidone; **and**
  - b. **ONE** of the following:
    - i. Aripiprazole; **or**
    - ii. Olanzapine; **or**
    - iii. Risperidone; **or**
    - iv. Quetiapine; **or**
    - v. Ziprasidone.

**If the above prior authorization criteria are met, Caplyta (lumateperone) will be authorized for 12-months.**

### **Medical Necessity Criteria for Reauthorization**

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. chart documentation shows the member has experienced clinical response to the requested therapy as evidenced by one of the following:
  - a. clinical improvement (e.g., reduction in intensity or severity of symptoms) since starting the requested medication; **or**
  - b. stability in condition (e.g., stabilizing mood, return to normal psychosocial functioning) since starting the requested medication; **AND**
2. The member maintains adherence to the prescribed dosing regimen as evidenced by pharmacy claims record.

### Experimental or Investigational / Not Medically Necessary

Caplyta (lumateperone) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Agitation in Dementia, Including Alzheimer's Disease
- Borderline Personality Disorder (BPD)
- Major Depressive Disorder (MDD)

### References

1. Caplyta (lumateperone) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; June 2023.
2. Corponi F, Fabbri C, Bitter I, et al. Novel antipsychotics specificity profile: a clinically oriented review of lurasidone, brexpiprazole, cariprazine and lumateperone. *Eur Neuropsychopharmacol.* 2019;29(9):971-985. doi:10.1016/j.euroneuro.2019.06.008
3. Corponi F, Fabbri C, Bitter I, et al. Novel antipsychotics specificity profile: a clinically oriented review of lurasidone, brexpiprazole, cariprazine and lumateperone. *Eur Neuropsychopharmacol.* 2019;29(9):971-985. doi:10.1016/j.euroneuro.2019.06.008
4. Keepers GA, Fochtmann LJ, Anzia JM, et al. The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia. *Am J Psychiatry.* 2020;177(9):868-872. doi:10.1176/appi.ajp.2020.177901
5. Reus VI, Fochtmann LJ, Eyster AE, et al. The American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia. *Am J Psychiatry.* 2016;173(5):543-546. doi:10.1176/appi.ajp.2015.173501
6. World Federation of Societies of Biological Psychiatry; Ihl R, Frölich L, Winblad B, et al. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the biological treatment of Alzheimer's disease and other dementias. *World J Biol Psychiatry.* 2011;12(1):2-32. doi:10.3109/15622975.2010.538083

### Clinical Guideline Revision / History Information

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