Oscar Clinical Guideline: Caplyta (lumateperone) (PG175, Ver. 4)

# 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 (or second generation antipsychotics) medication approved for 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, schizophrenia, and other serious mental health conditions require comprehensive treatment approaches. Treatment plans usually include both medication and non-medication approaches. Medicines, such as Caplyta (lumateperone), are often a part of treatment. Other medications in the group of second generation antipsychotics include, but are not limited to aripiprazole (Abilify), olanzapine (Zyprexa), quetiapine (Seroquel), risperidone (Risperidal), and ziprasidone (Geodon). Tolerance and response to antipsychotic agents vary, and those 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.

"Postpartum Psychosis" is a rare but serious mental health emergency characterized by sudden onset of psychotic symptoms shortly after childbirth. It is often characterized by acute onset of delusions, disorganized thoughts, hallucinations, and/or agitation. While it may occur as a manifestation of bipolar disorder, it can also present in patients without prior psychiatric history. Early recognition and treatment is critical due to risks to both mother and infant.

"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).

## Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

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:

## Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Bipolar Disorder

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

4. The medication is being requested for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression); *AND*
5. The member has tried and failed at least a one-month trial of ONE (1) of the following:
    a. Aripiprazole (Ability); *and/or*
    b. Asenapine (Saphris); *and/or*
    c. Lurasidone (Latuda)*; and/or*
    d. Quetiapine (Seroquel) immediate-release or extended-release*; and/or*
    e. Risperidone (Risperdal); *and/or*
    f. Olanzapine (Zyprexa) as monotherapy or in combination with fluoxetine (Prozac); *and/or*
    g. Paliperidone (Invega).

If the above prior authorization criteria are met, Caplyta (lumateperone) will be authorized for up to a lifetime.

Postpartum Psychosis

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

4. The member has postpartum psychosis as evidenced by ONE of the following:
    a. New onset psychotic symptoms (e.g., delusions, disorganized thoughts, hallucinations, agitation, bizarre behavior) in the postpartum period; *or*

b. Bipolar disorder with postpartum psychotic symptoms; features (e.g., delusions, disorganized thoughts, hallucinations, agitation, bizarre behavior); *or*
c. Primary mental disorder with psychotic symptoms during the peripartum period.

If the above prior authorization criteria are met, Caplyta (lumateperone) will be authorized for up to a lifetime.

Schizophrenia

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

4. The member has a diagnosis of schizophrenia; *AND*
5. 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 (Abilify); *and/or*
    b. Asenapine (Saphris); *and/or*
    c. Lurasidone (Latuda); *and/or*
    d. Olanzapine (Zyprexa); *and/or*
    e. Paliperidone (Invega); *and/or*
    f. Quetiapine (Seroquel); *and/or*
    g. Risperidone (Risperdal); *and/or*
    h. Ziprasidone (Geodon).

If the above prior authorization criteria are met, Caplyta (lumateperone) will be authorized for up to a lifetime.

Schizoaffective Disorder

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

4. The member has a diagnosis of schizoaffective disorder; *AND*
5. 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 (Invega); *and*
    b. ONE (1) of the following:
        i. Aripiprazole (Abilify); *or*
        ii. Asenapine (Saphris); *or*
        iii. Lurasidone (Latuda); *or*
        iv. Olanzapine (Zyprexa); *or*
        v. Quetiapine (Seroquel); *or*
        vi. Risperidone (Risperdal); *or*
        vii. Ziprasidone (Geodon).

If the above prior authorization criteria are met, Caplyta (lumateperone) will be authorized for up to a lifetime.

Adjunct Therapy of Major depressive disorder

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

4. The member has a diagnosis of major depressive disorder; *AND*
5. The member has demonstrated an inadequate response to at least 8-weeks of antidepressant therapy (e.g., delayed-release duloxetine, escitalopram, fluoxetine, extended-release paroxetine, sertraline, or extended-release venlafaxine); *AND*
6. Caplyta (lumateperone) is being prescribed for use as an adjunct to an antidepressant (e.g., delayed-release duloxetine, escitalopram, fluoxetine, extended-release paroxetine, sertraline, or extended-release venlafaxine); *AND*
7. The member is unable to use or has tried and failed TWO (2) of the following:
    a. Aripiprazole; *and/or*
    b. Olanzapine; *and/or*
    c. Quetiapine; *AND*
8. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Caplyta (lumateperone) will be authorized for up to a lifetime.

## 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. Caplyta (lumateperone) is not approved for dementia-related psychosis, and antipsychotics are associated with an increased risk of death in those with dementia.
- Borderline Personality Disorder (BPD). There are no high quality published studies supporting the safety and efficacy of Caplyta (lumateperone) for the management of BPD.

## References


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## Clinical Guideline Revision / History Information

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