

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Lumateperone (Caplyta)

Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as 2 week period without clinically significant improvement in target symptoms or side effects related to dosage form that cannot be resolved by adjusting dose or timing
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **lumateperone (Caplyta)** will be covered on the prescription drug benefit when the following criteria are met:

Schizophrenia

- Patient has a diagnosis of schizophrenia
- Patient is age 18 years or older
- Patient has failed an adequate trial[^] or patient has an allergy or intolerance* to 3 formulary antipsychotic agents (e.g. quetiapine, risperidone, olanzapine, aripiprazole, ziprasidone, lurasidone, clozapine, or a first-generation antipsychotic)

Bipolar Depression

- Patient has a diagnosis of major depressive episode due to bipolar I or bipolar II disorder
- Patient is age 18 years or older
- Patient has failed an adequate trial[^] or patient has an allergy or intolerance* to 2 of the following formulary options: lithium, valproate products, lamotrigine, or carbamazepine
- Patient has failed an adequate trial[^] or patient has an allergy or intolerance* to 2 of the following formulary options: quetiapine, olanzapine, or lurasidone or patient has prediabetes, diabetes, cardiovascular disease, body mass index (BMI) > 30 or documented contraindication, intolerance, or treatment failure to lurasidone

Major Depressive Disorder (MDD)

- Patient has a diagnosis of Major Depressive Disorder
- Patient is age 18 years or older
- Patient is currently taking an antidepressant (SSRI, SNRI, TCA, bupropion, mirtazapine)
- Patient has documented contraindication, intolerance, or treatment failure to at least 1 formulary options from the following medication classes: antidepressants

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and mood stabilizers (lithium or antiepileptic used for mood disorder such as divalproex)

- Patient has failed an adequate trial[^] or patient has an allergy or intolerance* to 2 formulary antipsychotic agents (e.g. quetiapine, olanzapine, aripiprazole)

Criteria for current or new Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **lumateperone (Caplyta)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has diagnosis of schizophrenia or major depressive episode due to bipolar I or bipolar II disorder, or major depressive disorder