Oscar Clinical Guideline: lurasidone (Latuda) (PG057, Ver. 6)

lurasidone (Latuda)

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

lurasidone (Latuda) is a second generation antipsychotic, also referred to as an atypical antipsychotic. It is FDA-approved for:

1. Treatment of schizophrenia in patients 13 years of age or older
2. Treatment of major depressive episodes associated with bipolar I disorder (bipolar depression) in patients 10 years of age or older

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 lurasidone (Latuda), are often a part of treatment. 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

"Bipolar 1 Disorder" is a mental health condition which includes episodes of emotional highs (mania) and lows (depression). It may cause extreme changes in behavior and mood, such as feeling much happier or sadder than normal.

"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 psychiatric disorder involving chronic or recurrent psychosis and is commonly associated with impairments in social and occupational functioning.

"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 Initial Authorization

The Plan considers **lurasidone (Latuda)** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

For the treatment of Depressive Episodes Associated with Bipolar Disorder:

1. The requested medication is prescribed by or in consultation with a psychiatrist; ***AND***
2. The member is at least 10 years of age; ***AND***
3. The member has a diagnosis of bipolar disorder; ***AND***
4. The member meets **ONE** (1) of the following:
    a. is unable to use or has adequately tried and failed at least a one-month trial to **BOTH** of the following:
        i. quetiapine immediate-release or extended-release; ***and***
        ii. olanzapine and fluoxetine in combination; ***or***

b. is at higher risk of metabolic abnormalities (e.g., those with diabetes mellitus or hyperlipidemia); ***AND***

5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

For the treatment of Postpartum Psychosis:

1. The requested medication is prescribed by or in consultation with a psychiatrist; ***AND***
2. The member has postpartum psychosis as evidenced by **ONE** of the following:
    a. New onset psychotic symptoms in the postpartum period; ***or***
    b. Bipolar disorder with postpartum psychotic features; ***AND***
3. Clinical documentation shows **BOTH**:
    a. Acute psychotic symptoms (e.g., delusions, disorganized thoughts, hallucinations); ***and***
    b. At least **ONE** of the following:
        i. Agitation; ***and/or***
        ii. Bizarre behavior; ***and/or***
        iii. Documented significant change from baseline functioning; ***AND***
4. Clinical chart documentation is provided for review to substantiate the above listed requirements.

For the treatment of Schizophrenia:

1. The requested medication is prescribed by or in consultation with a psychiatrist; ***AND***
2. The member is 13 years of age or older; ***AND***
3. The member has a diagnosis of schizophrenia; ***AND***
4. 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; ***AND***
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

For the treatment of Schizoaffective Disorder:

1. The requested 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 has a diagnosis of schizoaffective disorder; ***AND***
4. 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; ***AND***
5. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met for the applicable indication, lurasidone (Latuda) will be approved 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

lurasidone (Latuda) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Clinical Guideline Revision / History Information

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