Clinical Policy: Lurasidone (Latuda)

Reference Number: CP.PMN.50
Effective Date: 09.01.15
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lurasidone (Latuda®) is an atypical antipsychotic.

FDA Approved Indication(s)

Latuda is indicated for the treatment of:

- Schizophrenia in adults and adolescents (13 to 17 years)
- Depressive episode associated with bipolar I disorder (bipolar depression) in adults and pediatric patients (10 to 17 years) as monotherapy
- Depressive episode associated with bipolar I disorder (bipolar depression) in adults as adjunctive therapy with lithium or valproate

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Latuda is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Bipolar Disorder (must meet all)**:**

1. Diagnosis of bipolar disorder;
2. Age ≥ 10 years;
3. Failure of two preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, each used for ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 120 mg per day for adults and 80 mg per day for pediatric patients.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Schizophrenia (must meet all)**:**

1. Diagnosis of schizophrenia;
2. Age ≥ 13 years;
3. Failure of two preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, each used

for ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 160 mg per day for adults and 80 mg per day for adolescents.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Latuda for bipolar disorder or schizophrenia and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Schizophrenia: 160 mg per day for adults and 80 mg per day for adolescents;
   b. Bipolar disorder: 120 mg per day for adults and 80 mg per day for pediatric patients.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	**Bipolar Disorder and Schizophrenia** Adults: 10 to 15 mg PO QD	30 mg/day
olanzapine (Zyprexa®)	**Schizophrenia** Initial: 5 to 10 mg PO QD; target: 10 mg PO QD **Bipolar Disorder** Monotherapy: 10 to 15 mg PO QD; adjunct to lithium or valproate: 10 mg PO QD	20 mg/day
quetiapine (Seroquel®)	**Schizophrenia** Initial: 25 mg PO BID; target: 400 to 800 mg/day **Bipolar Disorder** Initial: 50 mg PO BID; target: 400 to 800 mg/day	800 mg/day
risperidone (Risperdal®)	**Schizophrenia** Initial: 1 mg PO BID or 2 mg PO QD; target: 4 to 8 mg PO QD **Bipolar Disorder** 2 to 3 mg PO QD	Schizophrenia: 16 mg/day Bipolar Disorder: 6 mg/day
ziprasidone (Geodon®)	**Schizophrenia** 20 mg PO BID **Bipolar Disorder** Initial: 40 mg PO BID; target: 40 to 80 mg PO BID	160 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to Latuda or any components in the formulation
  - Concomitant use with a strong CYP3A4 inhibitor (e.g., ketoconazole)
  - Concomitant use with a strong CYP3A4 inducer (e.g., rifampin)
- Boxed warning(s):
  - Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Latuda is not approved for the treatment of patients with dementia-related psychosis.
  - Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients. Closely monitor for clinical worsening and emergence of suicidal thoughts and behaviors. Latuda is not approved for use in pediatric patients with depression.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia	Adults: 40 mg to 160 mg PO QD	160 mg/day
	Adolescents: 40 mg to 80 mg PO QD	80 mg/day
Bipolar depression (bipolar I disorder)	Adults: 20 mg to 120 mg PO QD	120 mg/day
	Pediatrics: 20 mg to 80 mg PO QD	80 mg/day

VI. Product Availability

Tablets: 20 mg, 40 mg, 60 mg, 80 mg, 120 mg

VII. References

1. Latuda Prescribing Information. Malborough, MA: Sunovion Pharmaceutical Inc.; March 2018. Available at: http://www.latuda.com/. Accessed November 30, 2019.
2. Lehman AF, Lieberman JA, Dixon LB et al. Practice guideline for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004 Feb;161(2 Suppl):1-56.
3. American Psychiatric Association Practice Guideline for the Treatment of Patients with Bipolar Disorder: Second Edition (2005). Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf. Accessed November 30, 2019.
4. Goodwin GM, et al. Evidence-based guidelines for treating bipolar disorder: Revised third edition recommendations from the British Association for Psychopharmacology. J Psychopharmacology. 2016;30(6):495-553.
5. Washburn JJ, et al. Treatment of pediatric bipolar disorder: a review. Minerva Psichiatr. 2011 March;52(1):21-35.
6. National Institute for Health and Care Excellence (NICE) clinical guideline on bipolar disorder: assessment and management (CG185). Available at: nice.org.uk/guidance/cg185. Accessed November 30, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New guideline created – replaces CP.PMN.56	08.15	08.15
Updated references and added general statement that the dose does not exceed the plan daily quantity limit.	04.16	05.16
Converted to new template; Removed age criteria as age is not an absolute contraindication per FDA labeling; Updated references.	03.17	05.17
1Q18 annual review: Policies combined for Centene Medicaid, Marketplace and Commercial lines of business; No significant changes from previous corporate approved policy; Age added per safety guidance endorsed by Centene Medical Affairs; Removed diagnosis of metabolic syndrome from Centene commercial bipolar criteria; References reviewed and updated.	11.14.17	02.18
No significant changes: add coverage criteria for monotherapy use in pediatric bipolar depression.	04.02.18	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.30.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.30.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy; HIM.PA.103.

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