

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 adults and adolescents 13 years of age or older.
2. Treatment of major depressive episodes associated with Bipolar I Disorder (bipolar depression) in those 10 years of age or older.
3. Treatment of major depressive episodes associated with Bipolar I Disorder (bipolar depression) in adults as adjunctive therapy with lithium and 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 lurasidone (Latuda), 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 (Risperdal), and ziprasidone (Geodon). 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 (1) 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 features (e.g., delusions, disorganized thoughts, hallucinations, agitation, bizarre behavior); *or*
 - c. Primary mental disorder with psychotic symptoms during the peripartum period; *AND*
3. 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 (Abilify); *and/or*
 - b. Olanzapine (Zyprexa); *and/or*
 - c. Risperidone (Risperdal); *and/or*
 - d. Paliperidone (Invega); *and/or*
 - e. Quetiapine (Seroquel); *and/or*
 - f. Ziprasidone (Geodon); *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 (Invega); *and*
 - b. ONE (1) of the following:
 - i. Aripiprazole (Abilify); *or*
 - ii. Olanzapine (Zyprexa); *or*
 - iii. Risperidone (Risperdal); *or*
 - iv. Quetiapine (Seroquel); *or*
 - v. Ziprasidone (Geodon); *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 up to a lifetime.

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.

References

1. Alonso-Pedrero L, Bes-Rastrollo M, Marti A. Effects of antidepressant and antipsychotic use on weight gain: A systematic review. *Obes Rev*. 2019;20(12):1680-1690. doi:10.1111/obr.12934
2. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), American Psychiatric Association, Arlington, VA 2013.
3. Arango C, Ng-Mak D, Finn E, Byrne A, Loebel A. Lurasidone compared to other atypical antipsychotic monotherapies for adolescent schizophrenia: a systematic literature review and network meta-analysis [published online November 22, 2019]. *Eur Child Adolesc Psychiatry*.
4. Arnold MJ. Management of Bipolar Disorder: Guidelines From the VA/DoD. *Am Fam Physician*. 2024 Jun;109(6):585-587. PMID: 38905567.
5. Arnold MJ. Management of First-Episode Psychosis and Schizophrenia: Guidelines From the VA/DoD. *Am Fam Physician*. 2024 May;109(5):482-483.
6. Aziz R. How to Choose an Antipsychotic in Schizophrenia. *The Carlat Psychiatry Report*, April 2020. Volume 18, Issue 4.
7. Bobo WV. The Diagnosis and Management of Bipolar I and II Disorders: Clinical Practice Update. *Mayo Clin Proc* 2017; 92:1532.
8. Calabrese JR, Pikalov A, Streicher C, Cucchiaro J, Mao Y, Loebel A. Lurasidone in combination with lithium or valproate for the maintenance treatment of bipolar I disorder. *Eur Neuropsychopharmacol*. 2017 Sep;27(9):865-876. doi: 10.1016/j.euroneuro.2017.06.013. Epub 2017 Jul 6.
9. Carlat D. Latuda: An Evaluation of Its Usefulness. *The Carlat Psychiatry Report*, Feb 2015. Volume 13, Issue 2.
10. Citrome L, Weiden PJ, McEvoy JP, et al. Effectiveness of lurasidone in schizophrenia or schizoaffective patients switched from other antipsychotics: a 6-month, open-label, extension study. *CNS Spectr*. 2014;19(4):330-339.
11. Cohen LS, Church TR, Freeman MP, et al. Reproductive Safety of Lurasidone and Quetiapine: Update from the National Pregnancy Registry for Psychiatric Medications. *J Womens Health (Larchmt)*. 2023 Apr;32(4):452-462. doi: 10.1089/jwh.2022.0310. Epub 2023 Jan 30.
12. Correll CU and Kane JM. Ranking Antipsychotics for Efficacy and Safety in Schizophrenia. *JAMA Psychiatry*, 2020; 77(3), p.225. doi:10.1001/jamapsychiatry.2019.3377
13. Correll CU, Findling RL, Tocco M, Pikalov A, Deng L, Goldman R. Safety and effectiveness of lurasidone in adolescents with schizophrenia: results of a 2-year, open-label extension study. *CNS Spectr*. 2022 Feb;27(1):118-128. doi: 10.1017/S1092852920001893. Epub 2020 Oct 20. Erratum in: *CNS Spectr*. 2022 Feb;27(1):129. doi: 10.1017/S1092852921000511.
14. Cruz N, Sanchez-Moreno J, Torres F, Goikolea JM, Valentí M, Vieta E. Efficacy of modern antipsychotics in placebo-controlled trials in bipolar depression: a meta-analysis. *Int J Neuropsychopharmacol*. 2010;13(1):5-14. doi:10.1017/S1461145709990344
15. Dayabandara M, Hanwella R, Ratnatunga S, Seneviratne S, Suraweera C, de Silva VA. Antipsychotic-associated weight gain: management strategies and impact on treatment adherence. *Neuropsychiatr Dis Treat*. 2017;13:2231-2241. doi:10.2147/NDT.S113099

16. DelBello MP, Goldman R, Phillips D, Deng L, Cucchiaro J, Loebel A. Efficacy and safety of lurasidone in children and adolescents with bipolar I depression: a double-blind, placebo-controlled study. *J Am Acad Child Adolesc Psychiatry*. 2017;56(12):1015-1025.
17. Grunze H, Vieta E, Goodwin GM, et al. The World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the biological treatment of bipolar disorders: acute and long-term treatment of mixed states in bipolar disorder. *World J Biol Psychiatry*. 2018;19(1):2-58. doi:10.1080/15622975.2017.1384850
18. Hasan A, Falkai P, Wobrock T, et al; World Federation of Societies of Biological Psychiatry (WFSBP) Task Force on Treatment Guidelines for Schizophrenia. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, part 1: update 2012 on the acute treatment of schizophrenia and the management of treatment resistance. *World J Biol Psychiatry*. 2012;13(5):318-378. doi:10.3109/15622975.2012.696143
19. Javed A, Arthur H, Curtis L, Hansen L, Pappa S. Practical guidance on the use of lurasidone for the treatment of adults with schizophrenia. *Neurol Ther*. 2019;8(2):215-230. doi:10.1007/s40120-019-0138-z
20. Jena M, Mishra A, Mishra BR, Nath S, Maiti R. Effect of lurasidone versus olanzapine on cardiometabolic parameters in unmedicated patients with schizophrenia: a randomized controlled trial. *Psychopharmacology (Berl)*. 2020;237(11):3471-3480. doi:10.1007/s00213-020-05628-3
21. Judd LL, Akiskal HS, Schettler PJ, et al. The long-term natural history of the weekly symptomatic status of bipolar I disorder. *Arch Gen Psychiatry* 2002; 59:530.
22. 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
23. Latuda (lurasidone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; January 2025.
24. Lehman AF, Lieberman JA, Dixon LB, et al; American Psychiatric Association; Steering Committee on Practice Guidelines. Practice guideline for the treatment of patients with schizophrenia, second edition. *Am J Psychiatry*. 2004;161(2)(suppl):1-56.
25. Loebel A, Cucchiaro J, Silva R, et al. Lurasidone monotherapy in the treatment of bipolar I depression: a randomized, double-blind, placebo-controlled study. *Am J Psychiatry*. 2014 Feb;171(2):160-8. doi: 10.1176/appi.ajp.2013.13070984.
26. Loebel A, Silva R, Goldman R, et al. Lurasidone Dose Escalation in Early Nonresponding Patients With Schizophrenia: A Randomized, Placebo-Controlled Study. *J Clin Psychiatry*. 2016 Dec;77(12):1672-1680. doi: 10.4088/JCP.16m10698.
27. McEvoy JP, Citrome L, Hernandez D, et al. Effectiveness of lurasidone in patients with schizophrenia or schizoaffective disorder switched from other antipsychotics: a randomized, 6-week, open-label study. *J Clin Psychiatry*. 2013 Feb;74(2):170-9. doi: 10.4088/JCP.12m07992.
28. McQuaid JR, Buelt A, Capaldi V, et al. The Management of Major Depressive Disorder: Synopsis of the 2022 U.S. Department of Veterans Affairs and U.S. Department of Defense Clinical Practice Guideline. *Ann Intern Med*. 2022 Oct;175(10):1440-1451. doi: 10.7326/M22-1603. Epub 2022 Sep 20. PMID: 36122380.
29. Miller JN, Black DW. Schizoaffective disorder: a review. *Ann Clin Psychiatry*. 2019; 31(1):47-53.
30. Muñoz-Negro JE, Cuadrado L, Cervilla JA. Current Evidences on Psychopharmacology of Schizoaffective Disorder. *Actas Esp Psiquiatr*. 2019; 47(5):190-201.
31. Murru A, Hidalgo D, Bernardo M, et al. Antipsychotic switching in schizoaffective disorder: A systematic review. *World J Biol Psychiatry*. 2016 Oct;17(7):495-513. doi: 10.3109/15622975.2015.1012225. Epub 2015 Mar 9.
32. Nakamura M, Ogasa M, Guarino J, et al. Lurasidone in the treatment of acute schizophrenia: a double-blind, placebo-controlled trial. *J Clin Psychiatry*. 2009 Jun;70(6):829-36. doi: 10.4088/JCP.08m04905. Epub 2009 Jun 2.

33. National Institute for Health and Clinical Excellence (NICE), National Collaborating Centre for Mental Health. Psychosis and schizophrenia in children and young people: recognition and management. 2013. <https://www.nice.org.uk/guidance/cg155>[PubMed 26065063]
34. Osseur DN. The Psychopharmacology Algorithm Project at the Harvard South Shore Program: An update on management of behavioral and psychological symptoms in dementia. *Psychiatry Res.* 2021;295:113641. doi:10.1016/j.psychres.2020.113641Potkin SG, Ogasa M, Cucchiaro J, Loebel A. Double-blind comparison of the safety and efficacy of lurasidone and ziprasidone in clinically stable outpatients with schizophrenia or schizoaffective disorder. *Schizophr Res.* 2011 Nov;132(2-3):101-7. doi: 10.1016/j.schres.2011.04.008. Epub 2011 Sep 1.
35. Stroup TS, Marder S. Schizophrenia in adults: maintenance therapy and side effect management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com>. Accessed June 21, 2022.
36. Suppes T, Kroger H, Pikalov A, Loebel A. Lurasidone adjunctive with lithium or valproate for bipolar depression: A placebo-controlled trial utilizing prospective and retrospective enrolment cohorts. *J Psychiatr Res.* 2016 Jul;78:86-93. doi: 10.1016/j.jpsychires.2016.03.012. Epub 2016 Mar 31.
37. Swetlik C, Cohen LS, Kobylski LA, Sojka ET, Killenberg PC, Freeman MP, Viguera AC. Effects of Prenatal Exposure to Second-Generation Antipsychotics on Development and Behavior Among Preschool-Aged Children: Preliminary Results From the National Pregnancy Registry for Psychiatric Medications. *J Clin Psychiatry.* 2024 Mar 13;85(1):23m14965. doi: 10.4088/JCP.23m14965. PMID: 38488388.
38. Treatment and Management of Mental Health Conditions During Pregnancy and Postpartum: ACOG Clinical Practice Guideline No. 5. *Obstet Gynecol.* 2023 Jun 1;141(6):1262-1288. doi: 10.1097/AOG.0000000000005202. PMID: 37486661.
39. Viguera AC, McElheny SA, Caplin PS, Kobylski LA, Rossa ET, Young AV, Gaccione P, Góez-Mogollón L, Freeman MP, Cohen LS. Risk of Poor Neonatal Adaptation Syndrome Among Infants Exposed to Second-Generation Atypical Antipsychotics Compared to Antidepressants: Results From the National Pregnancy Registry for Psychiatric Medications. *J Clin Psychiatry.* 2023 Jan 4;84(1):22m14492. doi: 10.4088/JCP.22m14492. PMID: 36602927.
40. Yatham LN, Chakrabarty T, Bond DJ, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) recommendations for the management of patients with bipolar disorder with mixed presentations. *Bipolar Disord.* 2021;23(8):767-788. doi:10.1111/bdi.13135
41. Yatham LN, Kennedy SH, Parikh SV, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. *Bipolar Disord.* 2018;20(2):97-170. doi:10.1111/bdi.12609

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