

Clinical Policy: Atypical Antipsychotics

Reference Number: NH.PMN.56

Effective Date: 02.12

Last Review Date: 04.25

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The following are Atypical Antipsychotics requiring prior authorization: Brexpiprazole (Rexulti®), Clozapine (Clozaril®), Iloperidone (Fanapt®), Clozapine (Fazaclo®), Paliperidone ER (Invega®), Lurasidone (Latuda®), Pimavanserin (Nuplazid®), Risperidone (Risperdal®), Asenapine (Saphris®, Secuado®), Quetiapine ER (Seroquel XR®), Olanzapine (Zyprexa®), Olanzapine (Zyprexa Zydis®), Olanzapine-Samidorphan (Lybalvi).

FDA Approved Indication(s)

Atypical Antipsychotics are indicated for the below indications (varies dependent on medication):

1. Schizophrenia, or other psychotic disorders
2. Schizoaffective Disorder
3. Bipolar Disorder
4. Autism
5. Adjunct to Depression Therapy
6. Hallucinations and delusions associated with Parkinson's disease psychosis.

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 Atypical Antipsychotics are **medically necessary** when the following criteria are met:

I. Initial/Continued Approval Criteria

- A. Non-preferred Atypical Antipsychotics will require a prior authorization request from the prescriber with rationale for use of the intended drug therapy. Acceptable rationale may include: prior trial and failure of at least one preferred Atypical Antipsychotics or contraindications to PDL drugs, and/or diagnoses specific to the drug requested OR clinically unacceptable risk to switching to preferred agent.
- B. Requested non-preferred Atypical Antipsychotic must be appropriate to age and diagnoses as approved by the Food and Drug Administration. Continuity of care may be applied individually depending on the health plan, State mandates, transition between health care settings, and member eligibility.

Approval duration: 12 Months

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II. Continued Therapy

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy

Approval duration: 12 Months

III. References

1. Clinical Pharmacology, on-line. Drug monographs. Accessed 9/2012.
2. Prescribing information (drug specific).

| Revision | Date |
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| Updated indications and references. | 02.12 |
| Description revised. Listed out PDL agents and non-PDL agents separately. Changed criteria language to better describe step therapy. References updated. | 02.13 |
| Removed ST for olanzapine, quetiapine, and ziprasidone. Removed ST for non-PDL drugs and replaced with required PA. Changed status of Seroquel XR to non-PDL. Changed status of Abilify to PA. Added Abilify Maintena as a non-PDL drug. Added COC language noting that it may be applied variably depending on Health plan, state mandates, transition between health care settings, and member eligibility. References updated. | 08.13 |
| Change brand section to list all products (not specific to preferred/non-preferred status). Removed injectables from the brand section (as they have a separate guideline). Removed the following from special instructions section: all AAPs are indicated for the treatment of schizophrenia. However the other FDA approved indications vary by drug (i.e. not all AAPs are approved for autism, etc)." | 08.14 |
| Added other psychotic disorders to FDA labeled indications. Removed maximum tolerated dose from criteria A | 07.15 |
| Annual review, no changes | 10.16 |
| Added Brexpiprazole (Rexulti) to drug list | 11.16 |
| Annual review, no changes | 10.17 |
| Added Cariprazine (Vraylar) to list of medications. Removed note about Aripiprazole requiring prior authorization | 01.18 |
| Updated template. Removed generic clozapine, ziprasidone, olanzapine, quetiapine immediate release, and risperidone oral tablets and disintegrating tablets from brand section as no prior authorization is required for the generic formulation and brand name would be reviewed under the brand name policy. | 01.19 |
| Updated template | 02.19 |
| Added Pimavanserin (Nuplazid) to list as well as appropriate indications | 04.19 |
| Annual review. No update. | 07.20 |
| Added new product Olanzapine-samidorphan (Lybalvi) to policy | 07.21 |
| 3Q 2022 annual review: no significant changes | 07.22 |
| Changed to trial and failure of 1 preferred agent and added unacceptable risk language | 01.23 |
| Removed Vraylar as it is now a preferred option | 06.23 |
| Annual Review, no changes | 06.24 |
| Annual review, no significant changes | 04.25 |

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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

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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.

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