

## Clinical Policy: Atypical Antipsychotic Agents

Reference Number: OH.PHAR.PPA.37

Effective Date: 01.20

Last Review Date: 07.20

Line of Business: Medicaid

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

### Description

#### ANTIPSYCHOTICS, SECOND GENERATION, ORAL

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ARIPIPRAZOLE tablet (generic of Abilify®) OLANZAPINE (generic of Zyprexa®) CLOZAPINE (generic of Clozaril®) QUETIAPINE (generic of Seroquel®) RISPERIDONE (generic of Risperdal®) ZIPRASIDONE (generic of Geodon®)	LATUDA® (lurasidone) QUETIAPINE ER (generic of Seroquel XR®) FANAPT® (iloperidone) SAPHRIS® (asenapine)	ABILIFY DISCMELT® (aripiprazole) ABILIFY MYCITE® (aripiprazole with IEM) ARIPIPRAZOLE solution (generic of Abilify®) CLOZAPINE RAPID DIS(generic of Clozaril®) FAZACLO® (clozapine) OLANZAPINE ODT (generic of Zyprexa® Zydis) PALIPERIDONE (generic of INVEGA®) REXULTI® (brexpiprazole) VERSACLOZ® (clozapine oral suspension) VRAYLAR™ (cariprazine capsule) CAPLYTA™ (lumateperone) SECUADO® (asenapine)

#### ANTIPSYCHOTICS, SECOND GENERATION, AGENTS FOR PARKISON'S PSYCHOSIS\*

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
		NUPLAZID™ (pimavanserin)

#### ANTIPSYCHOTICS, SECOND GENERATION and SSRI COMBINATION

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"



	A trial of no less than fourteen days each of at least two preferred second generation oral antipsychotics or step therapy products	FLUOXETINE/OLANZAPINE (generic of Symbyax®)
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**ANTIPSYCHOTICS, SECOND GENERATION, LONG-ACTING INJECTABLES +**

<b>NO PA REQUIRED "PREFERRED"</b>	<b>PA REQUIRED "NON-PREFERRED"</b>
ABILIFY MAINTENA® (aripiprazole) ARISTADA™ (aripiprazole lauroxil) ARISTADA™ Initio (aripiprazole lauroxil) INVEGA SUSTENNA® (paliperidone) INVEGA TRINZA® (paliperidone) PERSERISTM (risperidone) RISPERDAL CONSTA® (risperidone) ZYPREXA RELPREVV® (olanzapine)	

+ Long-Acting Injectable Antipsychotics may be billed by the pharmacy if they are not dispensed directly to the patient. If not administered by the pharmacist, the drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy.

**FDA Approved Indication(s)**

- Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved indications

**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 the medications listed in the above tables are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Prescribed indication is FDA-approved or supported by standard pharmacopeias**

(must meet all):

1. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than thirty days each of at least two preferred or step therapy products unless one of the following:
  - a. Allergy to preferred medications
  - b. Contraindication to or drug interaction with preferred medications
  - c. History of unacceptable/toxic side effects to preferred medications

- d. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
    - e. If the requested medication is an orally disintegrating tablet, the member is unable or unwilling to swallow the standard tablet/capsule dosage form
  2. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than thirty days of at least one preferred product unless one of the following:
    - a. Allergy to preferred medications
    - b. Contraindication to or drug interaction with preferred medications
    - c. History of unacceptable/toxic side effects to preferred medications
    - d. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
    - e. If the requested medication is an orally disintegrating tablet, the member is unable or unwilling to swallow the standard tablet/capsule dosage form
  3. Clozapine or lurasidone (pregnancy category B) may be approved if member is pregnant
  4. If medication is Abilify Mycite it must be prescribed by a psychiatrist following an aripiprazole serum blood level draw indicating need for further investigation of adherence
  5. If medication is Nuplazid (must meet all):
    - a. Patient is diagnosed with Parkinson's disease and has psychotic symptoms (hallucinations and/or delusions) that started after Parkinson's diagnosis
    - b. These psychotic symptoms are severe and frequent enough to warrant treatment with an antipsychotic AND are not related to dementia or delirium
    - c. The patient's other medications for Parkinson's Disease have been reduced or adjusted and psychotic symptoms remain OR patient is unable to tolerate adjustment of these other medications
    - d. There has been inadequate clinical response to a trial of no less than thirty days of either quetiapine or clozapine OR these therapies cannot be utilized
    - e. An exemption to the criteria will be granted for prescribing doctors with a neurology specialty to a patient with a history of an anti-Parkinson's agent
  6. If medication is fluoxetine/olanzapine (Symbyax) member must have had a trial of no less than fourteen days each of at least two preferred second generation oral antipsychotics or step therapy products

**Approval duration: 12 months****II. 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 policy CP.PMN.53 for Medicaid or evidence of coverage documents.

**III. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

- Dosing varies by drug product. See FDA approved dosing and administration.

*Appendix C: Contraindications / Boxed Warnings*

- Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

**IV. Dosage and Administration**

- A. Varies by drug product. See FDA approved dosing and administration

**V. Product Availability**

- A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability

**VI. References**

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.19	
Added Caplyta (lumateperone) and Secuado (asenapine) to list of non-preferred second generation antipsychotics	07.20	

**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.

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**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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