

## Clinical Policy: Antipsychotic Medications in Children Under 18

Reference Number: AZ.CP.PMN.08

Effective Date: 07.2016

Last Review Date: 07.2020

Line of Business: Arizona Medicaid (AzCH-CCP and Care1st)

Revision Log

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

### Description

Antipsychotic Medications in Children Below Age Edits

### FDA approved indication

With the exception of risperidone, antipsychotics have not been approved for use in children less than 6 years old. There are few randomized controlled trials to demonstrate safety and efficacy in this population. Certain antipsychotics including clozapine and long-acting injectable antipsychotics have not been FDA approved in children and adolescents less than 18 years old. These products are not first line in this population. In general, the validity of the diagnosis of schizophrenia and bipolar disorder in patients <6 years old has not been established.

### Policy/Criteria

*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that oral antipsychotics (excluding clozapine) for children under 6 years of age and clozapine or long-acting injectable antipsychotics for children/adolescents between 6 and 18 years of age are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Antipsychotics For Children Less Than 6 Years of Age (must meet all):

1. Child diagnosed, per current DSM criteria, with one of the following disorders (a, b, c or d):
  - a. Bipolar Spectrum Disorder;
  - b. Schizophrenia Spectrum Disorder (schizophrenia, schizoaffective and schizophreniform disorders);
  - c. Tourette's or other tic disorder;
  - d. Autism Spectrum Disorder;
2. Prescribed by or in consultation with a psychiatrist;
3. Psychosocial issues and non-medical interventions are being addressed by the clinical team (a, b, and c):
  - a. Documentation of comprehensive mental health assessment (*see Appendix B*) occurring before request for antipsychotic medications;

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- b. Documentation of non-medication alternatives, evidence-based psychotherapeutic interventions that have been attempted to address symptoms for 3-6 months before request for antipsychotic medications;
- c. Documentation must include information on the expected outcomes and an evaluation of potential adverse events;
4. Request is for an antipsychotic medication other than clozapine;
5. Member must have a trial of low dose aripiprazole or risperidone prior to approval of other agents;
6. Dose does not exceed the FDA maximum dose;

#### **Approval duration: 6 months**

### **B. Antipsychotics in Children/Adolescents between 6-18 years of age** (must meet all):

1. Diagnosis, per current DSM criteria, with one of the following disorders (a or b):
  - a. Schizophrenia;
  - b. Spectrum Disorder (schizophrenia, schizoaffective and schizophreniform disorders);
2. Prescribed by or in consultation with a psychiatrist;
3. Request is for clozapine or long-acting injectable antipsychotic;
4. Psychosocial issues and non-medical interventions are being addressed by the clinical team (a and b):
  - a. Documentation of comprehensive mental health assessment (Appendix B) occurring before request for antipsychotic medications;
  - b. Documentation must include information on the expected outcomes and an evaluation of potential adverse events;
5. Failure of a  $\geq 4$  week trial of 2 preferred antipsychotics at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. For long-acting injectable requests, member has a history of non-adherence to oral antipsychotic therapy and has established tolerability to the preferred oral agent for the requested injectable (for new injectable paliperidone starts, member establishes tolerability to preferred oral risperidone or paliperidone if contraindication to risperidone exists);
7. Dose does not exceed the FDA maximum recommended dosage.

#### **Approval duration: 6 months**

### **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): AZ.CP.PMN.53 for Arizona Medicaid.

## **II. Continued Therapy**

### **A. Antipsychotics For Children Less Than 6 Years of Age** (must meet all):

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;

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2. Documentation of positive response to therapy [labs, sign/symptom reduction, etc.];
3. If request is for a dose increase, new dose does not exceed FDA approved maximum daily dose.

**Approval duration: 1 year**

#### **B. Antipsychotics in Children/Adolescents between 6-18 years of age** (must meet all):

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Documentation of positive response to therapy [labs, sign/symptom reduction, etc.];
3. If request is for a dose increase, new dose does not exceed FDA approved maximum daily dose.

**Approval duration: 1 year**

#### **C. 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): AZ.CP.PMN.53 for Arizona 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 – AZ.CP.PMN.53 for Arizona Medicaid.

### **IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: General Information*

#### **1. A comprehensive mental health assessment includes:**

- A comprehensive assessment of the full range of psychiatric symptoms and disorders, as well as impairment from these symptoms and disorders.
- A full developmental assessment.
- A full medical history, including a sleep history.
- A relevant medical work-up, physical examination and nutritional status evaluation.
- If relevant, an assessment of school functioning including academic, behavioral, and social aspects.

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- An assessment of family psychiatric history, which includes past and current history of parental psychiatric illnesses, substance abuse and treatment history of parents, parent figures (e.g., step-parent), siblings, and other relatives.
  - An assessment of family structure and functioning, parent-child relationship and interaction.
  - An assessment of environmental risk factors and stressors including any history of abuse (physical, sexual) or neglect, traumatic life events, domestic violence, economic instability, etc.
  - Reference: <http://www.medicaidmentalhealth.org/>
2. Dosing range for risperidone Tourette's in children under 6 has not been establish. Low initial doses 0.25mg/day recommended with usual effective range 1-4mg per day. Mean effective rate for adolescents over 7 year old was 2.5mg/day. This indication is "off label"
3. Dosing range for aripiprazole in children under 6 has not been established.

#### Appendix C: Therapeutic Alternatives

N/A

#### V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
risperidone(Risperdal)	Bipolar disorder	Not established in children under 10 starting dose 0.125mg max dose 1.5mg/day	3 mg/day
	Schizophrenia Spectrum Disorder* <i>*Dose from Florida guideline based on expert opinion</i>	Starting dose 0.125mg, max dose 1.5mg/day <i>Dosing not established, based on expert opinion</i>	3mg/day
	Autism Spectrum Disorder	Age 5-17 $\geq$ 20 kg: 1mg/day Age 5-17 $\leq$ 20kg: 0.5mg/day	Age 5-9: 3mg/day
	Tourette's	Not established in children under 6: 0.25mg-4mg	6mg/day
aripiprazole(Abilify)		1mg/day <i>Dosing not established, based on expert opinion</i>	7.5mg/day

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#### VI. Product Availability

Drug	Availability
risperidone (Risperdal)]	<p>Oral disintegrating tablets (ODT): 0.25 mg 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg</p> <p>Oral Solution: 1 mg/ml</p> <p>Oral tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg</p>
aripiprazole (Abilify)	<p>Oral disintegrating tablets (ODT): 10 mg , 15 mg</p> <p>Oral Solution: 1 mg/ml</p> <p>Oral tablets: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg,</p>

#### VII. References

1. Pliska SR, Greenhill LL, Crismon ML, et al. The Texas children's medication algorithm project: report of the Texas census conference panel on medication treatment of childhood deficit/hyperactivity disorder. Part 1. *J Am Academy Child Adolescent Psychology*. 2003;39(7):920-92
2. Correll CU, Manu P, et al. Cardiometabolic risk of second-generation antipsychotic medications during first time use in children and adolescents. *JAMA*. 2009; 302(16):1765-73.
3. McClellan J, Kowatch R, Findling RL. Practice parameter for the assessment and treatment of children and adolescent with bipolar disorder. *J AM Child Adolesc Psychiatry*. 2007; 46:107-126.
4. Schur S, Sikich L, Findling, et al. Treatment recommendations for the use of antipsychotics for aggressive youth (TRAAY) Part I: Review. *J AM Acad Child Adolesc Psychiatry*. 2003; 2:132-143.
5. Pappadoulos E, MacIntyre J, Crismon L, et al Treatment recommendations for the use of antipsychotics for aggressive youth (TRAAY) Part II: Review. *J AM Acad Child Adolesc Psychiatry*. 2003; 42 (2):145-161.
6. Kowatch R, DelBello M. The use of mood stabilizers and atypical antipsychotics in children and adolescents with bipolar disorders. *CNS Spectrums*. 2003; 8(4): 273-280.
7. Bartlett J. Childhood-onset schizophrenia; what do we really know?. *Health Psychol Behav Med*. 2014 Jan 1; 2(1); 735-747.
8. Florida Medicaid Drug Therapy Management Program for Behavioral Health. Principles of Practice Regarding the Use of Psychotherapeutic Medication in children Under 6. <http://www.medicaidmentalhealth.org/>; [http://www.medicaidmentalhealth.org/assets/file/Guidelines/POP\\_ASD&ID\\_Under%206.pdf](http://www.medicaidmentalhealth.org/assets/file/Guidelines/POP_ASD&ID_Under%206.pdf)
9. Arizona Health care Cost Containment System (AHCCCS), AHCCCS Behavioral Health System Practice Tools: Psychiatric and Psychotherapeutic Best Practices for Children: Birth Through Five Years of Age. Effective date 07/01/2016. Accessed 6/2020.

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<https://www.azahcccs.gov/PlansProviders/Downloads/GM/ClinicalGuidanceTools/PsychiatricandPsychotherapeuticBestPracticesforChildrenBirthThroughFiveYearsofAge.pdf>

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template Added requirement of risperidone or aripiprazole. Added definition of comprehensive mental health assessment.	03.18	4.18
Reviewed, renumbered and rebranded.	09.18	10.18
Updated logo	07.19	07.19
Added clozapine and LAI criteria for age < 18; Reformatted text.	02.20	07.20
2020 Annual review: references reviewed and updated	07.20	07.20
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21

### **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

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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.

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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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