

Clinical Policy: Antipsychotic Medications in Children Under 6 years Old

Reference Number: AZ.CP.PMN.08

Effective Date: 07.2016

Last Review Date: 07.2019

Line of Business: Arizona Medicaid

Revision Log

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

### **Description**

Antipsychotic Medications in Children Under 6 years Old

### **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.

### **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 that antipsychotics for children under 6 years of age are **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria (A,B and C required)**

##### **A. Child diagnosed, per current DSM criteria, with one of the following disorders:**

1. Bipolar Spectrum Disorder
2. Schizophrenia Spectrum Disorder (schizophrenia, schizoaffective and schizophreniform disorders)
3. Tourette's or other tic disorder
4. Autism Spectrum Disorder

##### **B. For indications above, all of the following must be met:**

1. Psychosocial issues and non-medical interventions are being addressed by the clinical team.
2. Documentation of comprehensive mental health assessment (Appendix B) occurring before request for antipsychotic medications.
3. 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.
4. Documentation must include information on the expected outcomes and an evaluation of potential adverse events.

##### **C. If A and B above are met, must have trial of low dose aripiprazole or risperidone prior to other agents being approved.**

**Approval duration: 6 months**

#### **D. Other diagnoses/indications**

1. Refer to AZ.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## **II. Continued Therapy**

### **A. 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**

## **III. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

N/A

*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.
- 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

**IV. 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
Dose from Florida guideline based on expert opinion	Schizophrenia Spectrum Disorder	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 ≥ 20 kg: 1mg/day  Age 5-17 ≤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

**V. Product Availability**

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

**VI. 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*. 200;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.

## CLINICAL POLICY

### Antipsychotic Medications in Children Under 6 years Old



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. 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)
8. 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 3/18. <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	09.18
Updated logo	07.19	07.19

#### **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.

## CLINICAL POLICY

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