

## WVCHIP Provider Prescribing Guidelines for Antipsychotics for Children

- There is some evidence suggesting that antipsychotics are effective for certain psychiatric disorders in children and adolescents, the majority of the studies are short-term open-label trials.<sup>1</sup>
- The FDA has included Abilify<sup>®</sup>, Seroquel<sup>®</sup> and Seroquel XR<sup>®</sup> in its additional black box warning for increased risk of suicidal thinking and behavior with the use of this class of medication in children, adolescents and young adults.<sup>2</sup>
- Except for clozapine and olanzapine, clinical trials do not show a dose-dependent relationship between second-generation antipsychotics (SGA) and metabolic complications.<sup>3</sup>
- Antipsychotics need to be monitored for serious metabolic effects. Some of these include weight gain, hyperglycemia, increased risk of type 2 diabetes, hyperlipidemia, agranulocytosis, serum prolactin elevation, and cardiovascular effects.<sup>4</sup>
- The use of more than one antipsychotic concurrently is not recommended. This practice increases issues with non-compliance, drug interactions, side effects and cost effectiveness. <sup>5</sup>
- The Texas Implementation of Medication Algorithms project does not recommend concurrent use of antipsychotics until stages 4 and 6 in its algorithm for schizophrenia. (Stage 4 is a combination with clozapine only.) <sup>5,6</sup>
- The American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity recommends the following screening measures for monitoring patients using antipsychotics. <sup>7, 1</sup>:
  - Personal Family History at baseline and annually (or as clinically indicated)
  - > Body Mass Index at baseline; four weeks; eight weeks; 12 weeks, and annually (or as clinically indicated)
  - > Waist Circumference at baseline and annually (or as clinically indicated)
  - > Blood Pressure at baseline: 12 weeks and annually (or as clinically indicated)
  - > Fasting Blood Glucose at baseline; 12 weeks, and annually (or as clinically indicated)
  - > Fasting Lipid profile at baseline; 12 weeks, and annually (or as clinically indicated)
  - White Blood Cell Count at baseline; 4 weeks; 8 weeks; 12 weeks, and annually (or as clinically indicated)

The screening measures apply to all ages since metabolic adverse events have recently been reported in children and adolescents who have been prescribed these medications.<sup>1,7</sup>

- Several lines of evidence support the safety and efficacy of antipsychotics for treating pediatric bipolar disorder.<sup>9</sup> Specifically the second-generation antipsychotics, risperidone, Ripiprazole, olanzapine, quetiapine and ziprasidone all have multicenter, randomized, double-blind placebo-controlled studies demonstrating efficacy as monotherapy in pediatric acute mania.<sup>9</sup>
- Clinical indications approved by the Food and Drug Administration (FDA) for antipsychotics in young people are limited to schizophrenia, behavioral symptoms in autism, Tourette's disorder, and mixed or manic bipolar episodes.<sup>10</sup>

Prior Authorization Guidelines Antipsychotics for Children Page 2

## **Required Documentation**

- **Evaluation** the patient must be evaluated initially and on an annual basis to assess the need for drug therapy, and monitor non-medication treatment alternatives, co-morbid disorders, dosage titration, adverse effects, and drug diversion and misuse.
- Diagnoses there are appropriate indications for the use of antipsychotic medications in young children with certain diagnoses which include: autism spectrum disorders, psychotic disorders, tic disorders, and severe agitation or aggression that may accompany severe mood and development disorders. Diagnosis must be confirmed and documented by prescriber.
- Prescribers may include Child Psychiatrist Board Certified; Child Psychiatrist Board Eligible; Psychiatrist Board Certified; Psychiatrist Board Eligible; ANCC Certified Family Psychiatric and Mental Health Nurse Practitioner; ANCC Certified Clinical Nurse Specialist in Child/Adolescent Psychiatric and Mental Health; Developmental-Behavioral Pediatrician Board Certified; Pediatric Neurology Board Certified. Please indicate specialty on the PA form (Attachment A).
- Polypharmacy PA requires a list of any psychoactive medications, concurrent medications, and previous medication trials in the preceding 12 months (other than the drug being requested).
- Target symptoms identify the primary target symptom the medication is being
  prescribed for so that family, mental health clinicians, teachers, and all involved adults can
  clarify and help determine the efficacy of the medication. The target symptoms are listed
  on Attachment A.
- Baseline/Annual Screening Measures Because of well-documented side effects
  regarding adverse effects on weight, glucose, and lipids, blood pressure, and white blood
  cell count, the PA requires a BMI measurement and official, most recent, lab results
  documented on each PA request. See the recommendations for baseline screening when
  prescribing for new atypical antipsychotic medications for members.
- PDL (Preferred Drug List) If the prescriber is requesting a non-preferred antipsychotic medication, clinical justification must be provided (e.g., failed trials of preferred medications including doses, length of treatment, clinical response, side effects, target symptoms). PA requests for brand medically necessary drugs must be submitted separately with clinical justification that the brand name drug is medically necessary.

  Members that are currently taking a drug that is used to treat, or is sensitive to, mental conditions, can continue to have their current prescription(s) covered even if their current medication is not on the WVCHIP Preferred Drug List when it is one of the following seven drug classes: Antipsychotics; Serotonin Selective Response Inhibitors (SSRI's); Central Nervous System Stimulants; Anticonvulsants; Sedative Hypnotic; Aliphatic Phenothiazine's; and Attention Deficit Disorder Drugs.
- **Member's age** the member's age must be within the FDA-approved age range for the medication being prescribed. The FDA-approved age range applies to the brand and generic version of the drug. See the table.

Atypical Antipsychotic	Indication	Target Symptoms	Age Range
Aripiprazole	Autism	Irritability	6-18
	Bipolar I Disorder	Manic or mixed episodes	8-17
	Schizophrenia	Positive and negative symptoms	13-17
Clozapine	Schizophrenia	Psychosis	8-18
Olazapine	Bipolar I Disorder	Manic or mixed episodes (acute and maintenance treatment)	13-17
	PDD	Aggression	6-14
	Schizophrenia	Positive and negative symptoms	13-17
Paliperidone	Schizophrenia	Positive and negative symtoms	12-17
Quetiapine	Schizophrenia	Positive and negative symptoms	13-17
	Bipolar I Disorder	Manic episodes	12-18
	Conduct Disorder	Aggression	12-17
Risperidone (Long acting	Autism	Irritability, aggression, communication, hyperactivity, affect regulation	2-18
injections not	Bipolar I Disorder	Manic or mixed episodes	10-17
indicated in children)	Development Disabilities, Sub-average IQ	Aggression, SIB	6-18
	Disruptive Behavior Disorders (including ADHD)	Conduct problems, irritability, hyperactivity, aggression	4-14
	Schizophrenia	Positive and negative symptoms	13-17
	Tourette Syndrome	Tics	7-17
Thiothixene			
Ziprasidone	Bipolar I Disorder	Mania	10-17
	Tourette Syndrome	Tics	7-17
Typical Antipsychotics			
Haloperidol	Behavioral Disorders	Conduct problems, irritability, hyperactivity, aggression	3-17
	Hyperactivity	Conduct problems, irritability, hyperactivity, aggression	3-17
	Psychosis	Manic or mixed episodes	3-17
Perphenazine	Schizophrenia	Positive & negative symptoms	12-17
Thioridazine	Schizophrenia	Positive & negative symptoms	6-17
Thiothixene	Schizophrenia	Positive & negative symptoms	12-17
Trifluoperzaine	Schizophrenia	Positive & negative symptoms	6-17

## **EXCLUSIONS**

Coverage of antipsychotics are not recommended in the following circumstances:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

## References

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- 2. FDA MedWatch- July 2009 Drug Safety Labeling Changes. Available at <a href="http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm172740.htm">http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm172740.htm</a>. Accessed
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- 8. Physician's Desk Reference, 62, Montvale, NJ; Thomson Healthcare, Inc; 2008
- 9. Singh, MK, Ketter, TA, Chang, KD. Atypical Antipsychotics for Acute Manic and Mixed Episodes in Children and Adolescents with Bipolar Disorder. *National Institute of Health (NIH-PA.); Drugs.* 2010 March 5; 70(4): 433-442.
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