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.[1]
- The FDA has included Abilify®, Seroquel® and Seroquel XR® 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.[2]
- Except for clozapine and olanzapine, clinical trials do not show a dose-dependent relationship between second-generation antipsychotics (SGA) and metabolic complications.[3]
- 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.[4]
- 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. [5]
- 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.) [5,6]
- 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. [7, 1]:
  - **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.[1,7]

- Several lines of evidence support the safety and efficacy of antipsychotics for treating pediatric bipolar disorder.[9] 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.[9]

- 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.[10]

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 injections not indicated in children)	**Autism**	**Irritability, aggression, communication, hyperactivity, affect regulation**	**2-18**
	Bipolar I Disorder	**Manic or mixed episodes**	**10-17**
	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

1. Jin H, et al. Use of clinical markers to identify metabolic syndrome in antipsychotic-treated patients. *J Clin Psychiatry;* 2010; 71(10):1273-1278.
2. FDA MedWatch- July 2009 Drug Safety Labeling Changes. Available at http://www.fda.gov/Safety /MedWatch/SafetyInformation/ucm172740.htm. Accessed
3. Simon V, et al. Are weight gain and metabolic side effects of atypical antipsychotics dose dependent? A literature review. *J Clin Psychiatry*; 2009 Jul; 70(7):1041-50.
4. Wolters Kluwer Health Inc. Facts & Comparisons E-Answers, 2010. Accessed (?)
5. Argo T, et al. Texas Medication Algorithm Project Procedural Manual: Schizophrenia Treatment Algorithms, Revised April 2008, http://www.dshs.state.tx.us/mhprograms/pdf/schizophreniamanual060608.pdf.
6. Goren J, et al. Development and delivery of a quality improvement program to reduce antipsychotic polytherapy. *J Manag Care Pharm;* 2010 Jul-Aug; 16(6):393-401.
7. American Diabetes Association; American Psychiatric Association; American Association of Clinical Endocrinologists; North American Association for the Study of Obesity (2004). Consensus development conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care*; 2004; 27(2):596-601.
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.
10. Stephen Crystal, Mark Olfson, Cecilia Huang, Harold Pincus and Tobias Gerhard, *Broadened Use of Atypical Antipsychotics: Safety, Effectiveness, and Policy Challenges,* Health Affairs, 28, no. 5 (2009): w770-w781 (Published online July 21, 2009; 10.1377/hlthaff.28.5.w770)

Antipsychotics for Children Prior Authorization Form

West Virginia Children's Health Insurance Program
Drug Prior Authorization Form
(website link; www.chip.wv.gov)

Rational Drug Therapy Program
WVU School of Pharmacy
PO Box 9511 HSCN
Morgantown, WV 26506
Fax: 1-800-531-7787
Phone: 1-800-847-3859

Providers are required to complete Prior Authorization Drug form for Atypical Antipsychotic Drugs for Children and submit the documentation to the Rational Drug Therapy Program (RDTP) at (800) 847-3859 or fax form to (800) 531-7787.

Patient Name (Last) (First) (MI)	WV CHIP ID #	Date of Birth (MM/DD/YY)
Prescriber Name (Last) (First) (MI)		
Prescriber Address (Street) (City) (State) (ZIP)		
Prescriber 10-Digit NPI #	Phone # (111-222-3333)	Fax # (111-222-3333)

Confidentiality Notice: This document contains confidential health information that is protected by law. This information is intended only for the use of the individual or entity names above. The intended recipient of this information should destroy the information after the purpose of its transmission has been accomplished or is responsible for protecting the information from any further disclosure. The intended recipient is prohibited from disclosing this information to any other party unless required to do so by law. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken en reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately and arrange for the return or destruction of these documents. Thank you.

Important Notes: Prior authorization for medical necessity does not guarantee payment. The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization.

Check One: ☐ Age < 6 years ☐ Age 6 years to <18 years			
Provider Type or Specialty:			
Medication Request: ☐ New ☐ Continuation	Patient: ☐ Male ☐ Female	Ht:	Wt: BMI:
Antipsychotic Medication/Strength:		Quantity:	
Directions:			

Target Symptoms: (Check all that apply) ☐ Severe Aggression ☐ Self-Injurious Behavior ☐ Extreme Impulsivity ☐ Extreme Irritability ☐ Psychotic Symptoms ☐ Other

DIAGNOSIS : ☐ ADHD ☐ Autism/PDD ☐ Schizophrenia ☐ ODD

☐Disruptive Behavior d/o ☐Bipolar Disorder ☐ Other: ICD Code:

Functional Impairment: ☐ 1 (Low) ☐ 2 ☐ 3 ☐ 4 ☐ 5 (Severe)

Have metabolic monitoring labs* (fasting lipids and glucose) been performed within the last 6 months? ☐ Yes ☐ No

Are the lab values within normal range? ☐ Yes ☐ No

If the answer is no, have the labs been ordered? ☐ Yes ☐ No

Has an assessment for Tardive Dyskinesia been done in the last 6 months? AIMS: ☐ Yes ☐ No DISCUSS: ☐ Yes ☐ No

Next Appointment Date:

Current Therapy (Pharmacological and Non-Pharmacological):

If the drug being requested is a non-preferred drug on the WVCHIP Preferred Drug List, has the preferred drug(s) been attempted in the past? ☐ Yes ☐ No

Indicate clinical justification why a non-preferred drug is necessary over a preferred drug.

Attestation: Your signature certifies that the above request is medically necessary, does not exceed the medical needs of the member, and is documented in your medical records. Medical/Pharmacy records must be made available upon request.

SIGNATURE – Prescriber Date Signed:

Required for Peer Review: Copies of medical records (diagnostic evaluation and recent chart notes), the original prescription and any related lab results. The provider must retain copies of all documentation for five years.

RDTP: ☐ Approval not Recommended ☐ Approval Recommended for _____months

Date: