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## Disclaimer

## Medical Policy Committee Approval History

| Date | History and Revisions by the Medical Policy Committee |
|---|---|
| 11/2/2017 | • Approved by MPC. Enhanced Care Management and Measures of Compliance sections. Revised with CM, DM, QI, UM, BH and the Chief Medical Directors. |

## Addendum

### PRESCRIBING GUIDANCE: AHCA AND THE UNIVERSITY OF SOUTH FLORIDA

The University of South Florida (USF) College of Behavioral Community Sciences and the Agency for Health Care Administration (AHCA) published the *Florida Psychotherapeutic Medication Guidelines for Children and Adolescents.* The aim of the guidelines is to provide guidance to clinicians in using psychotherapeutic medication to treat children and adolescents with behavioral health conditions. The guidelines cover a range of conditions including ADHD, anxiety disorders, severe or chronic bipolar disorder, depression, impulsive aggression, insomnia disorder, obsessive-compulsive disorder (OCD), post-traumatic stress disorder in preschool-age children, early onset schizophrenia, and tic disorders.[50]

*Principles of Practice Regarding the Use of Psychotropic Medication in Children under Age 6* [50]

**Level 0** consists of the following components:

- Conducting a comprehensive multi-informant, multi-modal, multi-disciplinary assessment for those with positive screen; and
- Using validated measures for assessing psychiatric symptoms and impairment in young children.

Recommended measures* of early childhood symptoms include:

- Ages 16 to 30 months: Modified Checklist for Autism in Toddlers (M-CHAT)
- Ages 2 to 4 years old and 4 to 11 years old: Strengths and Difficulties Questionnaire (SDQ)
- Ages 3 to 21 years old: The Child /Adolescent Psychiatry Screen (CAPS)
- Ages 4 to 11 years old: Home Situations Questionnaire (HSQ)

* Links to measures listed above are available at http://medicaidmentalhealth.org/resourcesLinks/diagnosticTreatmentScales.cfm

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.
- An assessment of family psychiatric history which includes past and current history of parental psychiatric illnesses, substance abuse and treatment history of parents, parental figures (e.g., stepparent), 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 history of abuse (physical, sexual, neglect), traumatic life events, domestic violence, economic instability, etc.

**Level 1** begins with psychosocial treatment. Parental involvement is essential as well as involvement of other caregivers and/or school-based interventions as needed. In addition, Level 1 consists of the following components:

- Monitoring the child's response to treatment using reliable and valid measures of changes in targeted symptoms; and
- Except in rare cases, attempt a course of at least 12 weeks of psychosocial interventions before considering medication.

**Level 2** consists of first asking if medications are being considered – the clinician should first reassess diagnosis and diagnostic formulation. If a decision is made to initiate medication:

- Initiate with monotherapy. Start low, go slow.
- Except in rare cases, use monotherapy.
- After 6 to 9 months of stabilization, plan down titration trial to determine if the medication is still needed and effective, (taper or discontinuation trial).
- Continue psychosocial treatment during treatment with medication.
- Use of psychotherapeutic medication in children under the age of 24 months is not recommended unless there are rare and extenuating circumstances.

*Monitoring Parameters.* Suggested monitoring parameters for baseline and regular monitoring for side effects for second generation antipsychotics include:

- BMI
- Fasting glucose
- Vital signs
- Family history of dyslipidemia or diabetes
- Screening for Involuntary Movements (AIMS)
- Lipid profile in higher risk children (obese, positive family history, etc.)

**PRESCRIBING GUIDANCE: AACAP**

The American Academy of Child and Adolescent Psychiatry (AACAP) discusses the current state of research based on what is currently known regarding the six AAAs that have been marketed in the United States and have pediatric data; AAAs are presented in order of marketing release. Paliperidone and asenapine were recently approved but have no data available pertaining to their use in children and adolescents; these were not considered in the AACAP parameter.[2]

- **Clozapine.** For pediatric patients suffering from treatment refractory schizophrenia and for those youths who require antipsychotic treatment but who have experienced severe EPS with other agents, the following applies:

  *Schizophrenia* – ages 9 years and older (refractory that has failed with standard antipsychotic agents)
  Initial dose: 6.25 – 12.5 mg orally per day
  Mean effective dose (in trials): 200 – 300 mg orally per day
  Maximum dose: 300 mg orally per day

- **Risperidone.** Risperidone has the most substantive amount of methodologically stringent evidence about its use in children and adolescents. Studies have found that risperidone resulted in significant improvement in serious behavioral problems in children with autism ages 5-17. In youths with disruptive behavior disorders, a study examined the impact of long-term risperidone treatment in those ages 5-17 who initially responded to a 12 week trial of medication; significant differences in relapse rates indicated that prolonged treatment with risperidone was beneficial. Prospective studies have reported the effectiveness of risperidone in the treatment of youths with schizophrenia, disruptive behaviors in autism and other PDDs, disruptive behaviors in children with sub-average intelligence, and impulsive aggression in conduct disorder/disruptive behavior disorders.

  The Texas Children's Medication Algorithm project recommends the addition of an AAA for the treatment of comorbid ADHD and aggression not responsive to behavioral intervention and psychostimulants. Among child and adolescent literature, reports of worsening or new onset OCD symptoms in youths treated with risperidone have been published. The following dosing information applies:

  *Schizophrenia* – 3 years or older
  Initial dose: 0.5 mg orally once a day
  Titration dose: May increase in increments of 0.5 mg to 1 mg per day at interval of 24 hours or more, as tolerated.
  Target dose: 3 mg orally per day
  Maximum dose: 6 mg orally per day

*Autism* – Ages 5 to 17 years
Weight greater than 15 kg and less than 20 kg
Initial dose: 0.25 mg orally once a day
Titration: after a minimum of 4 days, may increase to 0.5 mg per day; maintain this dose for a minimum of 14 days; subsequent dose increases may be made in increments of 0.25 mg at intervals of 2 weeks or more, as tolerated
Recommended dose: 0.5 mg orally per day
Weight 20 kg or greater
Initial dose: 0.5 mg orally once a day
Titration: After a minimum of 4 days, may increase to 1 mg per day; maintain this dose for a minimum of 14 days; subsequent dose increases in increments of 0.5 mg at intervals of 2 weeks or more, as tolerated.
Recommended dose: 1 mg orally per day

*Bipolar* – 10 years or older
Initial dose: 0.5 mg orally once a day
Titration dose: May increase in increments of 0.5 mg to 1 mg per day at interval of 24 hours or more, as tolerated.
Target dose: 1 to 2.5 mg orally per day
Maximum dose: 6 mg orally per day

- **Olanzapine.** Of the AAAs, olanzapine's receptor binding profile most closely matches that of clozapine. One study reported the short-term efficacy of olanzapine in the treatment of adolescents with schizophrenia. Another reported the short-term efficacy of olanzapine in the treatment of adolescents with bipolar illness suffering from a manic or mixed episode. A third study compared olanzapine, risperidone and haloperidol use in psychotic youths; the study found olanzapine's effectiveness to be comparable to both haloperidol and risperidone. A final study of olanzapine, risperidone, and molindone noted that both AAAs did not have superiority to molindone in treating early onset schizophrenia spectrum disorders. That study also found that olanzapine showed the greatest amount of weight gain. Olanzapine may provide benefit to patients suffering from PDDs, anorexia and other eating disorders, and Tourette's syndrome.

  *Schizophrenia* – Age 6 to 13 years or older
  Initial dose: 2.5 to 5 mg orally once a day
  Target dose: 10 mg orally once a day; further dose adjustments, if needed, should occur at intervals of not less than 1 week in 2.5 to 5 mg increments/decrements.
  Maximum dose: 20 mg orally once a day

  *Bipolar* – Age 13 years or older (treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder)
  Initial dose: 2.5 to 5 mg orally once a day
  Target dose: 10 mg orally once a day; dose adjustments, if needed, should occur at intervals of not less than 1 week in 2.5 to 5 mg increments/decrements.
  Maximum dose: 20 mg orally once a day

- **Quetiapine.** One study found that in adolescents with mania, treatment with quetiapine plus divalproex sodium was associated with greater symptom reduction than treatment with quetiapine plus placebo. In another study quetiapine was effective in children and adolescents with bipolar mania as well as adolescent schizophrenia and OCD. Open-label trials have noted potential benefit for aggression in conduct disorder, psychosis, mania, and tic disorders.[2]

- **Ziprasidone.** A trial reported that low doses (20-40mg per day) of ziprasidone was superior to placebo in the treatment of 28 patients ages 7-17 years with Tourette's syndrome. Efficacy was also reported in the treatment of manic or mixed episodes in youths suffering from bipolar I disorder. However, an industry-sponsored trial of ziprasidone for early-onset schizophrenia was stopped due to concerns over lack of efficacy. Additionally, reports of improvement were found among youths with a variety of neuropsychiatric conditions, including schizophrenia, autism/PDD, major depression with psychosis, bipolar disorder, and psychosis. A small number of youths treated with intramuscular ziprasidone have described positive clinical outcomes without significant

side effects.[2] Ziprasidone does not have FDA approval in children and adolescents.

*Bipolar* – Age 10 years and older (for acute mania and maintenance therapy after stabilization)
Initial Dose: 25 mg orally twice daily (day 1)
Day 2: 50 mg orally twice daily
Day 3: 100 mg orally twice daily
Day 4: 150 mg orally twice daily
Day 5+: 200 mg orally twice daily
Target dose range: 400 to 600 mg /day based on response and tolerability
Maximum dose: 600 mg orally per day

*Schizophrenia* – Age 13 years and older
Initial Dose: 25 mg orally twice daily (day 1)
Day 2: 50 mg orally twice daily
Day 3: 100 mg orally twice daily
Day 4: 150 mg orally twice daily
Day 5+: 200 mg orally twice daily
Target dose range: 400 to 600 mg /day based on response and tolerability
Maximum dose: 600 mg orally per day

- **Aripiprazole.** Preliminary studies suggest that patients with mania, conduct disorder with aggression, and PDD/autism might benefit from treatment with aripiprazole. Studies describe efficacy for aripiprazole in both youths ages 10-17 suffering from manic or mixed states, adolescents ages 13-17 suffering from schizophrenia, and children with irritability associated with autistic disorder.[2]

  *Autism* – Age: 6 to 17 years
  Dose should be individualized according to tolerability and response.
  Initial dose: 2 mg orally once a day
  Dose titration: Increase dose to 5 mg orally once a day, with subsequent increases to 10 mg or 15 mg orally once a day if needed; dose adjustments in increments of up to 5 mg/day to occur at intervals of no less than 1 week.
  Maximum Dose: 15 mg orally once a day

  *Bipolar Disorder* – Age 10 years or older
  As monotherapy or as adjunctive therapy with lithium or valproate.
  Initial Dose: 2 mg orally once a day
  After 2 days: Titrate to 5 mg orally once a day
  After 4 days: Titrate to 10 mg orally once a day
  Target Dose: 10 mg orally once a day; dose increases, if needed should be in 5 mg increments at 2-week intervals in order to allow time to achieve steady state
  Maximum Dose: 30 mg per day

  *Schizophrenia* – Age: 13 years or older
  Initial Dose: 2 mg orally once a day
  After 2 days: Titrate to 5 mg orally once a day
  After 4 days: Titrate to 10 mg orally once a day
  Target Dose: 10 mg orally once a day; effective dose range 10 to 30 mg per day; however, clinical trials have not found doses exceeding 10 mg per day to be more effective; dose increases, if needed should be in 5 mg increments at 2-week intervals in order to allow time to achieve steady state
  Maximum Dose: 30 mg per day

The AACAP also published *A Guide for Community Child Serving Agencies on Psychotropic Medications for Children and Adolescents.* The document addresses the following areas:[36]

- Context for Prescribing Psychotropic Medications
- Phases in Treatment

- Issues in Prescribing
- Considerations for Child Serving Agencies
- Sources of Information about Psychotropic Medications

Psychotropic medicines are taken for the purpose of improving the emotional and behavioral health of a child or adolescent diagnosed with a mental health condition. Evidence shoes that psychotropic medications are both over and under-prescribed in this population. Prescribing requires a competent prescriber, optimally a child and adolescent psychiatrist, with training and qualifications in the use of these medications in this age group. Medication is one component of a comprehensive biopsychosocial treatment plan that must include other components such as a comprehensive treatment plan requires a collaborative, team effort. The term biopsychosocial recognizes the three domains that impact a youth's emotional and behavioral well-being that must be considered in creating a comprehensive treatment or service plan.[36]

Professionals in child serving agencies can best support the treatment of youth with a mental illness by ensuring access to a comprehensive diagnostic assessment including biopsychosocial formulation conducted by a qualified licensed mental health professional in collaboration with the youth and the family. Discussions and use of psychotropic medication should recognize and address an individual's and family's cultural beliefs. A comprehensive assessment will include options for support and treatment that extend beyond just prescribing medications.[36]

## SIDE EFFECTS

The AACAP note the following significant safety issues and concerns associated at treatment initiation and even with sustained use of second generation antipsychotics (SGA):[2]

- Weight gain, diabetes and hyperlipidemia;
- Cardiovascular problems (e.g., prolongation of QTc interval, orthostatic hypotension, tachycardia and pericarditis and coronary artery disease associated with weight gain);
- Neutropenia and potential agranulocytosis;
- Hepatic dysfunction;
- Elevation of prolactin levels;
- Electroencephalogram (EEG) abnormalities and possible seizure activity;
- Potential for the development of extrapyramidal symptoms, tardive dyskinesia and withdrawal dyskinesias;
- Neuroleptic malignant syndrome; and
- Formation of cataracts.

The AACAP *Practice Parameter* underscores the importance of prescribers in consulting the existing scientific literature before selecting the SGA agent. Currently, SGAs clozapine, risperidone, olanzapine, quetiapine, ziprasidone, paliperidone and aripiprazole have published pediatric clinical trial data, but the more recently FDA approved SGA, asenapine, has no data pertaining to its use in the young population. Since the current FDA-approved indication for SGA use in children and adolescents includes only schizophrenia, bipolar disorder and specific symptoms of autism, the clinician is strongly urged to consider alternative pharmacological or psychosocial treatments for these other specific problems (i.e., disruptive behavior disorders and aggression). The *Practice Parameter* also discusses Pregnancy and In Utero; Bone Reduction; Cardiovascular Effects; Endocrine and Metabolic Effects; and Loss of Appetite. To review the *Practice Parameter* in its entirety, click here.[2]

## PRESCRIBING GUIDANCE: AMERICAN PSYCHIATRIC ASSOCIATION (APA)

*American Psychiatric Association (APA)*

The APA created a workgroup consisting of members from the Council on Research and Quality Care (CRQC). The following highlights were published to accompany the APA's recommendations noted above:[9]

1. **Don't prescribe antipsychotic medications to patients for any indication without appropriate initial evaluation and appropriate ongoing monitoring.** Metabolic, neuromuscular and cardiovascular side effects are common in patients receiving antipsychotic medications for any indication, so thorough initial evaluation to ensure that their use is clinically warranted, and ongoing monitoring to ensure that side effects are identified, are essential. Components of an initial evaluation include:

- A thorough assessment of possible underlying causes of target symptoms including general medical, psychiatric, environmental or psychosocial problems;
- Consideration of general medical conditions; and
- Assessment of family history of general medical conditions (including metabolic, cardiovascular disorders).

Ongoing monitoring includes re-evaluation and documentation of dose, efficacy and adverse effects; and targeted assessment, including assessment of movement disorder or neurological symptoms; weight, waist circumference and/or BMI; blood pressure; heart rate; blood glucose level; and lipid profile at periodic intervals.

2. **Don't routinely prescribe two or more antipsychotic medications concurrently.** Research shows that use of two or more antipsychotic medications occurs in 4 to 35% of outpatients and 30 to 50% of inpatients. However, evidence for the efficacy and safety of using multiple antipsychotic medications is limited, and risk for drug interactions, noncompliance and medication errors is increased. Generally, the use of two or more antipsychotic medications concurrently should be avoided except in cases of three failed trials of monotherapy, which included one failed trial of Clozapine where possible, or where a second antipsychotic medication is added with a plan to cross-taper to monotherapy.

3. **Don't routinely prescribe antipsychotic medications as a first-line intervention for children and adolescents for any diagnosis other than psychotic disorders.** There are both on and off label clinical indications for antipsychotic use in children and adolescents. FDA approved and/or evidence supported indications for antipsychotic medications in children and adolescents include psychotic disorders, bipolar disorder, tic disorders, and severe irritability in children with autism spectrum disorders; there is increasing evidence that antipsychotic medication may be useful for some disruptive behavior disorders. Children and adolescents should be prescribed antipsychotic medications only after having had a careful diagnostic assessment with attention to comorbid medical conditions and a review of the patient's prior treatments. Efforts should be made to combine both evidence-based pharmacological and psychosocial interventions and support. Limited availability of evidence based psychosocial interventions may make it difficult for every child to receive this ideal combination. Discussion of potential risks and benefits of medication treatment with the child and their guardian is critical. A short and long term treatment and monitoring plan to assess outcome, side effects, metabolic status and discontinuation, if appropriate, is also critical. The evidence base for use of atypical antipsychotics in preschool and younger children is limited and therefore further caution is warranted in prescribing in this population.

*Florida Medicaid Drug Therapy Management Program for Behavioral Health at the University of South Florida (USF)*[50]

In collaboration with the Agency for Health Care Administration (AHCA), USF developed the *Florida Psychotherapeutic Medication Guidelines for Children and Adolescents*.

Children Under 6 Years Old

The guidelines note that the use of antipsychotic medications in preschoolers (children under six years old) which is generally "off-label" is not recommended and should only be considered under the most extraordinary circumstances. Disruptive aggression in autism is one such circumstance. Adequately powered studies have not been conducted in preschoolers. Before considering pharmacological treatment, the following guidelines are strongly recommended:

- Perform a developmentally-appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target and treatment plans clearly identified and documented.
- Comprehensive assessment must include evaluation of parental psychopathology and treatment needs, as well as family functioning.
- Psychosocial treatments should precede the use of psychotropic medications and should continue if medications are prescribed.

Antipsychotic Dosing Information for Children under Age 6* * Should only be used under rare circumstances.

General Procedures for Monitoring Side Effects of Antipsychotic Medication in Children and Adolescents

Conduct side effect and metabolic assessments and laboratory tests that are clinically relevant, comprehensive, and

based on established guidelines.

- Monitor for metabolic syndrome criteria when prescribing atypical antipsychotics, with three of five criteria met:
  - Waist circumference greater than 90% for age
  - BP if <10 years old, then >90% for blood pressure **OR** BP if > 10 years old then >130 systolic or >85 diastolic
  - Triglycerides greater than 150 or greater than 95% for age
  - HDL <40 or <5% for age
  - Fasting blood glucose >100 (If metabolic abnormalities, refer to primary care physician)
- Monitor for extrapyramidal side effects (EPS) associated with second-generation antipsychotic use utilizing at least one of the following:
  - The Abnormal Involuntary Movement Scale (AIMS)
  - The Extrapyramidal Symptom Rating Scale (ESRS)
  - Dyskinesia Identification System: Condensed User Scale (DISCUS)

  NOTE: Links to measures listed above are available at http://medicaidmentalhealth.org/resourcesLinks/diagnosticTreatmentScales.cfm
- Provide accessible information to parents and families about identifying and managing side effects, including lifestyle and nutritional changes, monitoring labs, etc.

For additional information on levels of care for specific behavioral health conditions, consult the USF guidelines available at http://www.medicaidmentalhealth.org under “Child Guidelines”.