2019
Autism Spectrum Disorder & Intellectual Developmental Disorder:
Florida Best Practice Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents
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Introduction, Purpose, and Process for Creating the Guidelines

Introduction
Children and adolescents living with Autism Spectrum Disorder (ASD) and/or Intellectual Disability [also known as Intellectual Developmental Disorder, (ID)] are a unique and vulnerable population with special healthcare needs. These conditions are chronic in nature and are defined by criteria listed in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). Major characteristics of Autism Spectrum Disorder and Intellectual Disability (Intellectual Developmental Disorder) are as follows:

- **Autism Spectrum Disorder (ASD):** A disorder characterized by persistent deficits in social communication and social interaction across multiple contexts, including restricted, repetitive patterns of behavior, interests, or activities causing significant impairments of functioning.

- **Intellectual Disability/Intellectual Developmental Disorder (ID):** A disorder characterized by both intellectual and adaptive functioning deficits in conceptual, social, and practical domains.

Given the early onset and life-long nature of these conditions, as well as the complexity of symptoms and high prevalence of comorbid conditions, these children and their families require a multi-faceted approach to care that integrates therapy, medication management, and community engagement. Treating children and adolescents with these conditions can be challenging, especially since empirically supported treatments are not always readily available.

Purpose
The purpose of the **2019 Autism Spectrum Disorder & Intellectual Developmental Disorder: Florida Best Practice Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents** is to provide recommendations for psychotherapeutic medication prescribing based on the latest evidence and clinical consensus for a range of severe behavioral health symptoms and diagnoses often seen in children and adolescents with ASD or ID.

Process for Creating the Guidelines
Every two years, the Florida Medicaid Drug Therapy Management Program for Behavioral Health organizes diverse array of stakeholders known as the Florida Expert Panel to review and update the Florida Best Practice Recommendations for ASD and ID. The 2019 Florida Expert Panel consisted of local and nationally recognized experts, academicians, medical directors of Florida Medicaid health plans and community mental health centers (CMHCs), child and adolescent psychiatrists, pediatricians, primary care providers, and pharmacists.

The 2019 Expert Panel met in Coral Gables, Florida on February 2, 2019 to review and update the previous version of the Florida Best Practice Psychotherapeutic Medication Recommendations, which was published after the last consensus meeting in 2017. For each condition, a child and adolescent psychiatrist who is a nationally recognized content expert conducted a full review, presented the findings to the expert panel, and made suggestions to the panel on proposed revisions. The expert panel then discussed the proposed revisions and reached a consensus about whether or not to revise and adopt a particular set of recommendations. The final recommendations are a product of both an in-depth review of the literature with an emphasis on...
the highest level of clinical evidence (e.g., randomized controlled trials, systematic reviews), expert consensus on the strength of the evidence, and consideration of safety and efficacy. The names of the meeting attendees and meeting presentations are available on the Program website at floridamedicaidmentalhealth.org. Financial disclosures are available upon request.

**Organization**

The *2019 Autism Spectrum Disorder & Intellectual Developmental Disorder: Florida Best Practice Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents (2019)* cover treatment recommendations for a range of behavioral health symptoms and conditions encountered in children and adolescents with ASD and ID, including hyperactive, impulsive, and inattentive symptoms; aggression; sleep disturbances; restricted, repetitive behaviors; mood symptoms; catatonia; and psychosis. This year, the guidelines include updates in the Principles of Practice, with a focus on recommendations for medication optimization and deprescribing psychotherapeutic medications when clinically indicated. The guidelines also include a section addressing complementary and alternative treatments that have been used for Autism Spectrum Disorders.

The guidelines are organized by levels of treatment recommendations, beginning with Level 0, which involves a thorough clinical assessment. Subsequent levels (Levels 1, 2, 3, etc.) are based on the strength of the scientific evidence and expert consensus regarding a particular medication or treatment option. In addition to the current evidence, the expert panel considers both safety and efficacy when assigning a treatment option to a particular level. Therefore, Level 1 has the strongest evidence and safety profile compared to subsequent levels.

After a thorough assessment, clinicians are encouraged to begin treatment at Level 1. In some cases (e.g., severe symptoms), clinicians may choose to initiate treatment at a different level based on clinical judgement in conjunction with best evidence and guideline recommendations. Any decision regarding treatment should take into consideration the best evidence, practice recommendations, benefit-to-risk ratio, current symptoms, and level of impairment.

**Disclaimer**

*Use of these guidelines in whole or in part is entirely the responsibility of the clinician. The authors and panel members bear no responsibility for treatment decisions and outcomes based on the use of these guidelines.*
Principles of Practice in the Context of ASD and ID

Level 0 - Evaluation and Comprehensive Assessment:
The goals of the initial evaluation and comprehensive assessment are to document the child’s performance levels; functional abilities in cognitive, language, and social domains; contributions of genetic/metabolic etiologies; and presence of comorbid medical/neurologic disorders such as epilepsy.

The evaluation and comprehensive assessment includes:

✦ Detailed developmental and symptom history to assess the full range of psychiatric symptoms and disorders, (i.e., irritability, inattention, impulsivity, aggressive behaviors, repetitive, restricted behaviors, anxiety, depression, psychotic symptoms, and sleep disturbances) as well as impairment from these symptoms and disorders. The use of rating scales is highly recommended (See Box 1 on page 7).

✦ A full medical history and physical examination, including: vision, hearing, and dental screening.

✦ Assessment of diet/nutritional deficiencies, seizures, sleep disturbances, gastrointestinal problems (e.g., constipation, gastric reflux), and other medical problems.

✦ Special consideration of developmental speech, language, communication, neuropsychological, and educational assessments.

✦ Medication history, including over-the-counter, complementary, and alternative medicine.

✦ Treatment history, including behavioral therapies, occupational therapy, speech therapy, physical therapy, all medication trials, and complementary and alternative treatments.

✦ Assessment of family structure and functioning, including a safety assessment of the environment to identify:
  ✷ Risk of harm to self or others
  ✷ Nighttime wandering
  ✷ Low safety awareness/ impulsivity (e.g., water safety)
  ✷ Signs of abuse and/or neglect

✦ Behavior inventory using validated rating scales and checklists to document the occurrence of specific behaviors. For a list of rating scales and diagnostic checklists, see Box 1 on page 7.

For updated links to rating scales and checklists, visit floridamedicaidmentalhealth.org.

Based upon results of history and physical examination, consider as clinically indicated:

✦ Metabolic evaluation

✦ Comprehensive psychological evaluation

✦ Neurological consultation

✦ Genetic consultation
Level 1 - Evidence-Based Psychosocial Treatment and Other Non-Pharmacological Interventions:

Start with evidence-based psychosocial and other non-pharmacological interventions (e.g., occupational therapy, speech/language therapy). **Pharmacotherapy is not the primary treatment for youth with ASD and ID.**

Early intervention is of paramount importance to address the symptoms of ASD. Aim non-pharmacological therapy at the most impairing target symptom first. Please note, the Florida Expert Panel has added recommendations specific to each condition reviewed. See Use of Psychotherapeutic Medications in Children and Adolescents with ASD and ID on page 9.

**Recommended psychosocial and non-pharmacological interventions:**

- Behavior therapy: e.g., Parent-Child Interaction Therapy (PCIT) for children under age 7; Parent Management Training (PMT) for children over age 7; Applied Behavior Analysis (ABA); Cognitive Behavior Therapy (CBT); and others
- Speech/language therapy
- Occupational therapy
- Physical therapy
- Social skills therapy
- Special educational services (academic and life skills)

Treat co-occurring medical problems (e.g., seizures).

*Note: Medication changes and reactions warrant consideration as to the cause of disruptive behaviors.*

Provide psychoeducation for parents/caregivers regarding ASD, ID, and co-occurring conditions.
Box 1.

**Recommended Rating Scales, Diagnostic Instruments, and Sleep Screening Tools.**

**Rating Scales:**
- Modified Checklist for Autism in Toddlers (M-CHAT)
- Childhood Autism Spectrum Test (CAST)
- Vanderbilt Assessment Scales
- Childhood Autism Rating Scale, Second Edition (CARS-2)*
- Social Communication Questionnaire (SCQ)*
- Social Responsiveness Scale, Second Edition (SRS-2)*
- Conners Rating Scales*
- Aberrant Behavior Checklist (ABC)*

*Not available in the public domain

**Diagnostic Instruments:**
- Autism Diagnostic Observation Schedule, Second Edition (ADOS-2)*
- Autism Diagnostic Interview — Revised (ADI-R)*

*Not available in the public domain

**Notes:**
- Both the ADOS-2 and ADI-R are the “Gold Standard” to support the diagnosis of ASD if administered by qualified raters.
- The ABC can be used to assess medication responses.
- ABC, Vanderbilt, and Conners Rating Scales assess specific behavioral domains but are not screening tools for ASD.

**Sleep Screening Tools:**
- BEARS Sleep Screening Algorithm: Ages 2 to 18 years
- Children’s Sleep Habits Questionnaire (CSHQ): Ages 4 to 12 years
- Sleep diaries

For updated links, visit floridamedicaidmentalhealth.org.
Special Considerations in Children under Age 6

Level 0 - Evaluation and Comprehensive Assessment:
Evaluation and comprehensive assessment. See Principles of Practice.
Use of rating scales is highly recommended. For a list of scales and checklists, see Principles of Practice and Box 1 on page 7.
For updated links to rating scales and checklists, visit floridamedicaidmentalhealth.org.

Early signs that may indicate a child under age 6 is at risk for ASD:
- No big smile or other warm, joyful expressions by six months or later
- No back-and-forth sharing of sounds, smiles, or other facial expressions by 9 months
- No babbling by 12 months
- No back-and-forth gestures such as pointing, showing, reaching, or waving by 12 months
- No words by 16 months
- No meaningful, two-word phrases (not including imitating or repeating) by 24 months
- Any loss of speech, babbling, or social skills at any age

Level 1 - Evidence-Based Psychosocial Treatment and Other Non-Pharmacological Interventions:
Start with evidence-based psychosocial and other non-pharmacological interventions (e.g., physical therapy, speech/language therapy). See Principles of Practice.

Note: Pharmacotherapy is not the primary treatment for youth with ASD and ID. The use of antipsychotic medications in children under 6 years of age is generally “off-label,” not recommended, and should only be considered under the most extraordinary circumstances.
Although not considered first line treatment in children with ASD and ID, depending on the severity of symptoms, some medications may be helpful. If the decision is made to use medication, monitoring for side effects is essential.

**GENERAL CONSIDERATIONS**

- Prior to beginning any treatment with psychotherapeutic medications:
  - Consider functional behavioral assessment to identify triggers/effects of maladaptive behavior.
  - Weigh risks/benefits of treating with psychotherapeutic medications.
  - Define target symptom domain and rule out medical etiology. Aim pharmacotherapy at the most impairing target symptoms first.
  - Obtain resting blood pressure, heart rate, weight, height, and body mass index (BMI) percentile at baseline and follow-up visits.
  - Baseline and follow-up electrocardiogram (ECG) are warranted if the child has a history or evidence of cardiac disease.

**CONSIDERATIONS WHEN TREATING WITH ANTIPSYCHOTIC MEDICATIONS**

*Note: See Table 1 on page 10 for full monitoring recommendations.*

- Prior to beginning treatment with antipsychotic medication:
  - Obtain height, weight, and BMI percentile.
  - Obtain baseline fasting glucose and lipid panel.
  - Complete baseline tardive dyskinesia screen (AIMS or DISCUS).
  - Treat concurrently with psychosocial interventions.

- At treatment initiation:
  - Clearly establish the goal of antipsychotic therapy, first targeting symptoms that are most impairing.
  - Start low, go slow.
  - Start with antipsychotic medications that have the greatest strength of evidence in pediatric populations (ie, risperidone or aripiprazole).
  - Use the minimum effective dose to minimize adverse effects.
  - Provide healthy lifestyle information.

- Follow-up medication monitoring:
  - Monitor BMI.
  - Obtain fasting blood glucose, hemoglobin A1c (HbA1c), lipid panel, and tardive dyskinesia screen at least every 6 months; repeat more frequently if there is rapid weight gain or signs of abnormal movement. Consider total insulin level in those with significant weight gain or early evidence of metabolic derangement.

- Not recommended:
  - Use of antipsychotic medication without concurrent psychosocial treatment(s).
  - Olanzapine (Zyprexa®) and olanzapine/fluoxetine (Symbyax®) as first or second-line agents; use in patients who are overweight or obese, dyslipidemic, or hyperglycemic.

*Note: Overweight is defined as BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% of ideal weight.*
# Recommended Routine Monitoring in Youth with ASD and ID Treated with Antipsychotic Agents

Table 1.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Baseline</th>
<th>Each visit</th>
<th>During Titration and at Target Dose</th>
<th>At 3 Months</th>
<th>At 6 Months</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal and family medical history</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>√</td>
</tr>
<tr>
<td>Treatment efficacy, new medications and interaction effects with antipsychotics</td>
<td>√</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Lifestyle behaviors</td>
<td>√</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Sedation/somnolence</td>
<td>√</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Calculate BMI percentile, BMI z score</td>
<td>√</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Sexual/reproductive dysfunction</td>
<td>√</td>
<td>—</td>
<td>√</td>
<td>√</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Parkinsonism (SAS or ESRS*), Akathisia (AIMS or ESRS*)</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>√</td>
<td>√</td>
<td>—</td>
</tr>
<tr>
<td>Fasting blood glucose, HbA1C and lipids</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>√</td>
<td>√</td>
<td>—</td>
</tr>
<tr>
<td>Tardive dyskinesia</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>√</td>
<td>—</td>
</tr>
<tr>
<td>Blood pressure and pulse</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>√</td>
</tr>
<tr>
<td>Liver function tests</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>√</td>
</tr>
</tbody>
</table>

Based on clinical consensus.
Table 1 (continued).

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Baseline</th>
<th>Each visit</th>
<th>During Titration and at Target Dose</th>
<th>At 3 Months</th>
<th>At 6 Months</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrolytes, full blood count, renal function</td>
<td>√</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>√</td>
</tr>
<tr>
<td>ECG†</td>
<td>If symptomatic or per guideline recommendations; see note below.</td>
<td>—</td>
<td>If symptomatic or per guideline recommendations; see note below.</td>
<td>If symptomatic or per guideline recommendations; see note below.</td>
<td>If symptomatic or per guideline recommendations; see note below.</td>
<td>If symptomatic or per guideline recommendations; see note below.</td>
</tr>
</tbody>
</table>

Notes: *AIMS: Abnormal Involuntary Movement Scale; ESRS: Extrapyramidal Symptom Rating Scale; SAS: Simpson Angus Rating Scale. ESRS not available in the public domain.

†ECG: Obtain ECG in cases of family history of sudden cardiac death in first degree relatives (males <50 years, females <55 years), prolonged QT syndrome, personal history of heart murmur, irregular heartbeat, tachycardia at rest, dizziness or syncope upon exertion, or in the case of co-treatment with another QTC prolonging medication. Check ECG at baseline, during titration, and annually when using ziprasidone.

**Use of Psychotherapeutic Medications in Children and Adolescents with ASD and ID (continued)**

**Personal and Family Medical History:**
- Include assessment for:
  - Metabolic Syndrome (e.g., obesity, arterial hypertension, diabetes, dyslipidemia)
  - Seizures and other neurological disorders
  - Current treatments
  - Potential interaction effects with antipsychotics (e.g., Fluoxetine and paroxetine may inhibit hepatic metabolism of aripiprazole and risperidone, increasing blood levels of aripiprazole and risperidone.)
  - Past medical history for coronary artery disease or coronary artery disease equivalent (i.e., diabetes mellitus, peripheral arterial disease, abdominal aortic aneurysm, and symptomatic carotid artery disease)
  - Premature coronary artery disease in first degree relative (males <55 years, females <65 years)
  - Personal history of heart murmur, irregular heartbeat, tachycardia at rest, or dizziness or syncope upon exertion
  - Past efficacy and adverse effects of medications in child/adolescent and/or family members

**Lifestyle Behaviors:**
- Diet, exercise, smoking, substance use, and sleep hygiene

**Sedation/Somnolence:**
- Youth with neurodevelopmental disorders are particularly prone to sleep disturbances due to many comorbid conditions, social stressors, and concurrent use of medications. Sleep hygiene should be optimized and reviewed at each visit. If sleep medications are administered, use caution as to the choice of medication and monitor for side effects.
**Use of Psychotherapeutic Medications in Children and Adolescents with ASD and ID (continued)**

**Fasting Blood Glucose, Hemoglobin A1c (HbA1c) and Lipids:**

- More frequent assessments may be necessary in high-risk patients (e.g., family history of diabetes, non-Caucasian ethnicity, BMI >95th percentile, weight gain >7% over 3 months or less, or weight gain >0.5 BMI z-score at any time point). HbA1c better identifies patients with pre-diabetes than fasting blood glucose alone. Consider total insulin level in high-risk individuals.

**Prolactin Elevation:**

- Monitor for clinical symptoms of hyperprolactinemia (i.e., signs or symptoms such as amenorrhea, oligomenorrhea, gynecomastia, galactorrhea, hirsutism, or erectile/sexual dysfunction) at every visit. Obtain serum prolactin levels if symptomatic. Draw prolactin level in the morning and approximately 12 hours after the last antipsychotic dose. The effects of asymptomatic, long-term hyperprolactinemia remain unclear (Ho et al, 2011).

**ECG:**

- Obtain in cases of family history of sudden cardiac death in first degree relatives (males <50 years, females <55 years), prolonged QT syndrome, personal history of heart murmur, irregular heartbeat, tachycardia at rest, dizziness or syncope upon exertion, or in the case of co-treatment with another QTc prolonging medication.
Table 2.

<table>
<thead>
<tr>
<th>Adverse Effect</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Weight gain and metabolic abnormalities</strong></td>
<td>✦ Healthy lifestyle counseling</td>
</tr>
<tr>
<td></td>
<td>✦ Begin or switch to antipsychotic with low adverse effect risk profile (i.e., lower metabolic risk).</td>
</tr>
<tr>
<td></td>
<td>✦ Consider targeted treatment for abnormal weight:</td>
</tr>
<tr>
<td></td>
<td>☑ Obtain blood pressure values.</td>
</tr>
<tr>
<td></td>
<td>☑ Initiate lipid-lowering diet for dyslipidemia.</td>
</tr>
<tr>
<td></td>
<td>☑ Refer to specialist (child psychiatrist, pediatric neurologist, or developmental pediatrician).</td>
</tr>
<tr>
<td></td>
<td>☑ Consider a trial of metformin.</td>
</tr>
<tr>
<td><strong>Neuromotor</strong></td>
<td>✦ Monitor for movement disorders in youth with ASD/ID; can be difficult due to stereotypy and repetitive behaviors.</td>
</tr>
<tr>
<td></td>
<td>✦ Comprehensively assess abnormal movements at baseline and follow-up with objective rating scales.</td>
</tr>
<tr>
<td></td>
<td>✦ Individualized strategy and family member participation may be necessary to facilitate treatment adherence.</td>
</tr>
<tr>
<td><strong>Parkinsonism, dystonia (EPS)</strong></td>
<td>✦ Reduce dose.</td>
</tr>
<tr>
<td></td>
<td>✦ Add anticholinergic medication.</td>
</tr>
<tr>
<td></td>
<td>✦ Switch to lower-risk agent.</td>
</tr>
<tr>
<td><strong>Akathisia</strong></td>
<td>✦ Reduce dose.</td>
</tr>
<tr>
<td></td>
<td>✦ Switch to lower-risk agent.</td>
</tr>
<tr>
<td><strong>Dyskinesia</strong></td>
<td>✦ Review indication.</td>
</tr>
<tr>
<td></td>
<td>✦ Consider stopping.</td>
</tr>
<tr>
<td></td>
<td>✦ Switch to lower-risk agent.</td>
</tr>
</tbody>
</table>
Medication Optimization and Deprescribing in Children and Adolescents with ASD and ID

**INTRODUCTION**

- Medication optimization for target symptoms in children with ASD and ID involves a systematic approach that takes into consideration current symptoms, level of impairment, indications for medication prescribing, evidence-base, and benefit-to-risk ratio.
- Routine evaluation of medications regimens is recommended to minimize the use of polypharmacy and potential medication-related adverse effects.
- One approach in determining whether a medication is being used appropriately or whether (and how) it can be stopped has been deprescribing.

**WHAT IS DEPREScribing?**

- Deprescribing is a structured approach to identifying and discontinuing medications when existing or potential harms outweigh existing or potential benefits.
- Deprescribing is not synonymous with medication cessation; rather, the goal is to use the minimum effective dose and lowest number of medications necessary to manage symptoms and maintain functioning.
- Deprescribing is its own process, requiring extreme caution and a certain skill on the part of the prescriber.

**RECOMMENDATIONS FOR MEDICATION OPTIMIZATION/DEPREScribing**

- Start with a comprehensive psychiatric assessment. Obtain information from collateral sources such as parents/family members, teachers/school, and other care providers. Refer to the Principles of Practice.
- Develop a comprehensive treatment plan, including evidence-based psychosocial interventions.
- Be clear about the reasons for deprescribing psychotherapeutic medication.
- Identify medications than can be reduced or discontinued.
- In cases of polypharmacy, reduce or discontinue only one medication at a time.
- Consider factors such as:
  - The target symptoms for which the medications are prescribed
  - Evidence-base for use
  - Medication benefit
  - Risk of medication-related adverse effects
  - Potential for drug-drug interactions.
- Start with medications:
  - Without a clear indication.
  - If after assessment, it remains unclear what symptoms the medication was targeting.
Medication Optimization and Deprescribing in Children and Adolescents with ASD and ID (continued)

- With the least evidence of efficacy for the symptoms the medication is prescribed to treat.
- Develop a monitoring plan, including safety risk monitoring.
- If symptoms recur once a medication is reduced or stopped, first wait and observe. Symptom exacerbation may be self-limited and related to medication withdrawal. Consider the presence of external stressors, and reinforce therapeutic support strategies.
- If symptoms persist, review the differential diagnosis and treatment plan. Consider updating the treatment plan if indicated.

Note: Special thanks to Megan Baker, MD, Clinical Assistant Professor in the Department of Child and Adolescent Psychiatry at the New York University School of Medicine for her input on these recommendations.
What is Complementary and Alternative Medicine (CAM)?

The National Center for Complementary and Integrative Health (NCCIH) defines “complementary” as a non-mainstream practice used together with conventional medicine and “alternative” medicine as a non-mainstream practice used in place of conventional medicine.

What CAM Therapies have been Tried in Children with ASD?

CAM therapies explored for symptomatic improvement in ASD can be broadly categorized into biologically-based and non-biologically based interventions.

- Biologically-based interventions include dietary interventions (for example, elimination diets, vitamin supplements, and herbal remedies); chelation therapy; and hyperbaric oxygen therapy.
- Non biologically-based CAM interventions include mind-body practices (for example, meditation, music therapy, yoga); manipulative and body-based treatments (for example, acupuncture); and energy medicine (homeopathy, Reiki).

What is the State of the Evidence for CAM Therapy in the Context of ASD?

- There is a lack of high-quality research on complementary and alternative approaches to treat symptoms of ASD.
- Treatments such as hyperbaric oxygen therapy and chelation therapy have no scientific evidence supporting their use for ASD symptoms and the risks outweigh known benefits.
- CAM treatments are not recommended to be used in place of conventional treatments.

For more information on complementary and alternative treatments in the context of Autism Spectrum Disorders, visit the National Institutes of Health’s National Center for Complementary and Integrative Health at https://nccih.nih.gov/health/autism.
Resources

Listed are some national and local resources for youth with ASD and/or ID.

National Resources
- Autism Speaks Autism Treatment Network (ATN)
- Centers for Disease Control and Prevention (CDC)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute of Mental Health (NIMH)
- Medical Investigation of Neurodevelopmental Disorders (MIND) Institute

Local Resources
- Center for Autism and Related Disabilities (CARD) – locations throughout Florida
- Autism Speaks, Florida
- Florida Developmental Disabilities Council
- Autism Society of Florida
- Family Network on Disabilities (FND)
- Reaching Potentials
- Healing Every Autistic Life (HEAL!)

For updated links to resources, visit floridamedicaidmentalhealth.org.
Working with Medicaid health plans and providers to:
- Improve behavioral health prescribing practices
- Improve patient adherence to medication
- Reduce clinical risks and medication side effects
- Improve behavioral and physical health outcomes

The following treatment guidelines are available on our website at floridamedicaidmentalhealth.org.
- Best Practice Recommendations for Women of Reproductive Age with Severe Mental Illness and Comorbid Substance Use Disorders
- Best Practice Psychotherapeutic Medication Guidelines for Adults
- Monitoring Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach
- Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents
- Autism Spectrum Disorder & Intellectual Developmental Disorder: Best Practice Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents

The Florida Pediatric Psychiatry Hotline is a free service that provides consultation about medication management.

Florida Pediatric Psychiatry Hotline
1-866-487-9507

Florida Medicaid Drug Therapy Management Program for Behavioral Health

For more information, visit us at floridamedicaidmentalhealth.org
The Florida Pediatric Psychiatry Hotline provides timely telephonic psychiatric and clinical guidance to primary care clinicians treating children with behavioral health conditions. The hotline enables primary care clinicians to get assistance for any child under their care and is highly rated by those using the service.

The Florida Pediatric Psychiatry Hotline is operated by the University of South Florida Division of Child and Adolescent Psychiatry and the Rothman Center for Neuropsychiatry in St. Petersburg, Florida. Tanya Murphy, MD., Maurice A. and Thelma P. Rothman Chair of Developmental Pediatrics and Professor in the Departments of Pediatrics and Psychiatry, and a team of certified child psychiatrists from the University of South Florida oversee the hotline and provide many of the consultations.

The goals of the Pediatric Psychiatry Hotline are to:

- Provide consultation about psychotherapeutic medications for children with behavioral health conditions.
- Facilitate a referral to a child psychiatrist or psychiatric ARNP when possible.
- Promote a collaborative relationship between primary care clinicians and child psychiatrists.

About the service:

- The hotline is free and related to consultation about medication management.
- Calls will be answered on non-holiday weekdays between 8:30 am and 4:30 pm.
- Most calls will be scheduled with a child psychiatrist within 1 to 4 hours.
- Telephone consultations are limited to 20 minutes per call.
- Only information relevant to medication management will be discussed. No patient names or other unique identifying information needs to be provided.
Youth with ASD and ID experience symptoms of hyperactivity, impulsivity, and inattention (ADHD) at higher rates than their neurotypical peers. Children and adolescents can benefit from the same evidence-based treatments used to treat ADHD uncomplicated by ASD.

**Level 0 - Comprehensive Assessment:**

See *Principles of Practice*. In addition, give special consideration to:

- Developmental history and cognitive assessment (neuropsychological or educational)
- ADHD symptom history
- Parent and teacher rating scales (e.g., Vanderbilt Assessment Scales, Conners Parent and Teacher Rating Scales)*
  
  **Note:** Conners Parent and Teacher Rating Scales are not in the public domain.
- Teacher behavior reports
- Involvement in community resources
- Physical examination (e.g., if history of staring spells or focal neurological signs: EEG, MRI).
- Safety concerns related to significant impulsivity (e.g., bolting away, darting across roads, excessive climbing).

**Level 1 - Methylphenidate or guanfacine monotherapy.**

If child has significant symptoms, consider methylphenidate or guanfacine as a first line medication.

- Use methylphenidate or guanfacine (both immediate-release and extended-release) with caution since adverse behavioral effects may be higher in youth with ASD and ID compared to normally developing youth with ADHD. Methylphenidate or guanfacine yield benefit in about 50% of children in the ASD and ID population for hyperactivity. Close monitoring is recommended, and lower dosing than expected may be required for tolerability.

- **Methylphenidate is favored over guanfacine for treatment of inattention without hyperactivity.**
  
  - Obtain resting blood pressure and heart rate at baseline and follow-up visits.
  
  - ECG is recommended if the child has evidence of cardiac disease or known family history of sudden death. Consult a pediatric cardiologist before initiating treatment.
  
  - Continue to increase dose until ADHD symptoms are adequately controlled, maximum recommended dosing is reached, or treatment-limiting side effects emerge.

Refer to Tables 3-7 on pages 23-29 for dosing recommendations.
Treatment of Hyperactive, Impulsive, and Inattentive Symptoms in the Context of ASD and ID (continued)

Level 2 - Combination therapy with methylphenidate and guanfacine OR atomoxetine:

- 2a. If partial response to monotherapy (i.e., methylphenidate or guanfacine alone), consider combination therapy with methylphenidate and guanfacine.
- 2b. Atomoxetine
  - Obtain resting blood pressure and heart rate at baseline and follow-up visits.
  - Consider ECG if there is evidence of cardiac disease or known family history of sudden death. Consult a pediatric cardiologist.
  - Consider liver function tests if on other medications or history of hepatic dysfunction.

Refer to Tables 3-7 on pages 23-29 for dosing recommendations.

Level 3 - Reassess and consult specialist.

- Refer to child and adolescent psychiatrist for consultation, or to another pediatric specialist (pediatric neurologist or developmental pediatrician) if indicated.
- Although limited evidence exists in the ASD/ID population, may consider use of an amphetamine preparation.
- Reassess psychosocial interventions that may enhance the efficacy of treatment. Psychosocial interventions such as parent management training may enhance the efficacy and acceptability of treatment.

Refer to Tables 3-7 on pages 23-29 for dosing recommendations.

Not recommended:

- Combination of two alpha-2 agonists (i.e., clonidine and guanfacine)
## Table 3.

### ADHD Medication Treatment for Children under Age 6

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Starting Dose Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methylphenidate and Amphetamine preparations</strong></td>
<td></td>
</tr>
<tr>
<td>Immediate-Release</td>
<td></td>
</tr>
<tr>
<td>Methylphenidate:</td>
<td></td>
</tr>
<tr>
<td>Immediate-release:</td>
<td></td>
</tr>
<tr>
<td>Ritalin®, Methylphenidate® Chewable Tablets, Methylphenidate® Oral Solution</td>
<td>1.25 mg tid – titrate as needed to doses not exceeding 1 mg/kg/day. Recommendations extrapolated from the Preschool ADHD Treatment Study (PATS).</td>
</tr>
<tr>
<td>Amphetamine:</td>
<td></td>
</tr>
<tr>
<td>Immediate-release:</td>
<td></td>
</tr>
<tr>
<td>Mixed amphetamine salts (Adderall®), D-amphetamine (Dexedrine®, Dextrostat®, ProCentra® Oral Solution, Zenzedi®). D- &amp; L-amphetamine (Evekeo®)</td>
<td>2.5 mg/day – titrate as needed to doses not exceeding 0.5 mg/kg/day. Amphetamine target dose is generally one-half to two-thirds of methylphenidate dose.</td>
</tr>
<tr>
<td><strong>Selective norepinephrine inhibitor</strong></td>
<td></td>
</tr>
<tr>
<td>Atomoxetine (Strattera®)</td>
<td>10 mg/day – titrate as needed to doses not to exceed 1.4 mg/kg/day. Recommendations extrapolated from the Kratochvil et al. 2011 study.</td>
</tr>
<tr>
<td><strong>Alpha-2 Agonists</strong></td>
<td></td>
</tr>
<tr>
<td>Alpha-2 Agonists:</td>
<td></td>
</tr>
<tr>
<td>Clonidine (Catapres®, KAPVAY®)</td>
<td>Starting dose not to exceed:</td>
</tr>
<tr>
<td>Guanfacine (Tenex®, Intuniv®)</td>
<td>0.05 mg/day (immediate-release clonidine, Catapres®)</td>
</tr>
<tr>
<td></td>
<td>0.1 mg/day (extended-release clonidine, KAPVAY®)</td>
</tr>
<tr>
<td></td>
<td>0.5 mg/day (immediate-release guanfacine, Tenex®)</td>
</tr>
<tr>
<td></td>
<td>1 mg/day (extended-release guanfacine, Intuniv ®)</td>
</tr>
<tr>
<td></td>
<td><strong>Monitor carefully for excessive sedation, increased irritability.</strong></td>
</tr>
<tr>
<td></td>
<td>Recommendations based on expert opinion.</td>
</tr>
</tbody>
</table>

**Notes:**

1. No FDA indication for children younger than 6 years old; based on Preschool ADHD Treatment Study results (Greenhill et al., 2006).
2. FDA indication for ADHD treatment of children 3-5 years old, but no clinical trial study results available.
3. No FDA indication for children younger than 6 years old; based on Kratochvil et al., 2011.
4. No FDA indication for ADHD except guanfacine extended-release (Intuniv®) and clonidine extended-release (KAPVAY®) in children 6 years and older; no clinical trial study results available for alpha-2 agonist use for ADHD in children below age 6 years old. There is no new data on extended-release stimulants in preschoolers, but the 2007 American Academy of Child and Adolescent Psychiatry guideline algorithm included extended-release formulations to address compliance concerns (Pliszka et al., 2007).

Continue titration until symptoms are adequately controlled, treatment-limiting side effects emerge, or maximum recommended daily dose is reached.
### Treatment of Hyperactive, Impulsive, and Inattentive Symptoms in the Context of ASD and ID (continued)

Table 4.

<table>
<thead>
<tr>
<th>Generic Class/Brand Name</th>
<th>Typical Starting Dose</th>
<th>FDA Max Dose/Day</th>
<th>Off-Label Max Dose/Day</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methylphenidate preparations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immediate-Release</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focalin® (dexmethylphenidate hcl tablet)</td>
<td>2.5 mg bid</td>
<td>20 mg</td>
<td>50 mg</td>
<td></td>
</tr>
<tr>
<td>Methylin® (methylphenidate hcl tablet)</td>
<td>5 mg bid</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td>Immediate-release stimulants are often used as initial treatment in children (&lt;16 kg), but have disadvantage of bid – tid dosing to control symptoms throughout the day.</td>
</tr>
<tr>
<td>Methylin® Solution (methylphenidate hcl oral solution)</td>
<td>5 mg bid</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td></td>
</tr>
<tr>
<td>Methylin® Chewable (methylphenidate hcl chewable tablet)</td>
<td>5 mg bid</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td></td>
</tr>
<tr>
<td>Ritalin® (methylphenidate hcl tablet)</td>
<td>5 mg bid</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td></td>
</tr>
<tr>
<td><strong>Intermediate-Release</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metadate ER® (methylphenidate hcl extended-release tablets)</td>
<td>10 mg qam</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td></td>
</tr>
<tr>
<td>Metadate CD® (methlypheidate hcl extended-release capsule)</td>
<td>20 mg qam</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td>Longer acting stimulants offer greater convenience, confidentiality, and compliance with single daily dosing but may have greater problematic effects on evening appetite and sleep.</td>
</tr>
<tr>
<td>Methylin ER® (methylphenidate hcl extended-release tablet)</td>
<td>10 mg qam</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td></td>
</tr>
<tr>
<td>Ritalin LA® (methylphenidate hcl extended-release tablet)</td>
<td>20 mg qam</td>
<td>60 mg</td>
<td>&gt;50 kg: 100 mg</td>
<td></td>
</tr>
</tbody>
</table>
Table 4 (continued).

<table>
<thead>
<tr>
<th>FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old: Methylphenidate Preparations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Generic Class/Brand Name</strong></td>
</tr>
<tr>
<td>--------------------------------</td>
</tr>
<tr>
<td><strong>Methylphenidate preparations (continued)</strong></td>
</tr>
<tr>
<td><strong>Extended-Release</strong></td>
</tr>
<tr>
<td>Aptensio XR® (methylphenidate hcl extended-release capsule)</td>
</tr>
<tr>
<td>Concerta® (methylphenidate extended-release tablet)</td>
</tr>
<tr>
<td>Cotempla XR-ODT® (methylphenidate extended-release orally disintegrating tablet)</td>
</tr>
<tr>
<td>Daytrana® patch (methylphenidate transdermal system)</td>
</tr>
<tr>
<td>Focalin XR® (dexamethylphenidate hcl extended-release capsule)</td>
</tr>
<tr>
<td>Quillivant XR® (methylphenidate hcl extended-release oral suspension)</td>
</tr>
<tr>
<td>QuilliChew ER® (methylphenidate hcl extended-release chewable tablet)</td>
</tr>
</tbody>
</table>

**Notes:**
Ritalin LA 60 mg (specific brand and dose) and Ritalin SR were discontinued for reasons other than safety and effectiveness. Ritalin LA brand drug is still available in 10 mg, 20 mg, 30 mg, and 40 mg capsules (i.e., doses other than 60 mg). The generic methylphenidate extended-release capsule is available in all doses, including 60 mg.

*Continue titration until symptoms are adequately controlled, treatment-limiting side effects emerge, or maximum recommended daily dose is reached.*
### Table 5. FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old: Amphetamine Preparations

<table>
<thead>
<tr>
<th>Generic Class/Brand Name</th>
<th>Typical Starting Dose</th>
<th>FDA Max Dose/Day</th>
<th>Off-Label Max Dose/Day</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amphetamine preparations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Immediate-Release</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adderall® (amphetamine mixed salts tablet)</td>
<td>5 mg daily – bid</td>
<td>40 mg</td>
<td>&gt;50 kg: 60 mg</td>
<td>Immediate-release stimulants are often used as initial treatment in children (&lt;16 kg) but have disadvantage of bid – tid dosing to control symptoms throughout the day. Note that all amphetamine immediate-release products have the same dosing recommendations.</td>
</tr>
<tr>
<td>Dexedrine® (dextroamphetamine immediate-release tablet)</td>
<td>5 mg daily – bid</td>
<td>40 mg</td>
<td>&gt;50 kg: 60 mg</td>
<td></td>
</tr>
<tr>
<td>Dextrostat® (dextroamphetamine immediate-release tablet)</td>
<td>5 mg daily – bid</td>
<td>40 mg</td>
<td>&gt;50 kg: 60 mg</td>
<td></td>
</tr>
<tr>
<td>Evekeo® (d- and l-amphetamine tablet)</td>
<td>5 mg daily – bid</td>
<td>40 mg</td>
<td>&gt;50 kg: 60 mg</td>
<td></td>
</tr>
<tr>
<td>Procentra Oral Solution® (d-amphetamine oral solution)</td>
<td>5 mg daily – bid</td>
<td>40 mg</td>
<td>&gt;50 kg: 60 mg</td>
<td></td>
</tr>
<tr>
<td>Zenzedi® (d-amphetamine tablet)</td>
<td>5 mg daily – bid</td>
<td>40 mg</td>
<td>&gt;50 kg: 60 mg</td>
<td></td>
</tr>
</tbody>
</table>
## Table 5 (continued).

### FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old: Amphetamine Preparations

<table>
<thead>
<tr>
<th>Generic Class/Brand Name</th>
<th>Typical Starting Dose</th>
<th>FDA Max Dose/Day</th>
<th>Off-Label Max Dose/Day</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amphetamine preparations (continued)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Extended-Release</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dexedrine Spansule® (dextroamphetamine sulfate extended-release capsule)</td>
<td>5–10 mg daily to twice per day</td>
<td>40 mg</td>
<td>Not yet known</td>
<td>Extended-release stimulants offer greater convenience, confidentiality, and compliance with single daily dosing but may have greater problematic effects on evening appetite and sleep. Adderall XR® capsule may be opened and sprinkled on soft foods.</td>
</tr>
<tr>
<td>Adderall XR® (amphetamine extended-release mixed salts capsule)</td>
<td>10 mg daily</td>
<td>6–12 years: 30 mg</td>
<td>6–12 years: 20 mg</td>
<td>Not yet known</td>
</tr>
<tr>
<td>Vyvanse® (lisdexamfetamine capsule)</td>
<td>20–30 mg daily</td>
<td>70 mg</td>
<td>Not yet known</td>
<td>Vyvanse® capsule can be opened and mixed with yogurt, water, or orange juice.</td>
</tr>
<tr>
<td>Dyanavel XR® 2.5mg/mL (amphetamine extended-release oral suspension)</td>
<td>2.5 to 5 mg daily</td>
<td>20 mg</td>
<td>Not yet known</td>
<td>For Dyanavel XR® do not substitute for other amphetamine products on mg-per-mg basis.</td>
</tr>
<tr>
<td>Adzenys XR-ODT® (amphetamine extended-release orally disintegrating tablet)</td>
<td>6.3 mg qam unless switched from Adderall XR (Refer to conversion schedule)</td>
<td>6–12 years: 18.8 mg</td>
<td>6–12 years: 12.5 mg</td>
<td>Not yet known</td>
</tr>
</tbody>
</table>

**Note:** Continue titration until symptoms are adequately controlled, treatment-limiting side effects emerge, or maximum recommended daily dose is reached.
Table 6.

| FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old: SNRIs and Alpha-Adrenergic Agonists |
|---|---|---|---|---|
| **Generic Class/Brand Name** | **Typical Starting Dose** | **FDA Max Dose/Day** | **Off-Label Max Dose/Day** | **Comments** |
| **Selective norepinephrine reuptake inhibitor** | | | | |
| Strattera® (atomoxetine) | Start at 10 mg/day and increase by 10 mg/week | Lesser of 1.4 mg/kg or 100 mg | No off-label recommendation. | Not a Schedule II medication. Consider if active substance abuse or severe side effects of stimulants (mood lability, tics). Give qam or divided doses bid (for effects on late evening behavior). Do not open capsule; must be swallowed whole. Monitor closely for suicidal thinking and behavior, clinical worsening, or unusual changes in behavior. |
| **Alpha- adrenergic agonists** | | | | |
| Intuniv® (guanfacine ER) | 1 mg daily then titrate up by 1 mg increments once per week | Lesser of 0.12 mg/kg or 4 mg daily (6-12 years) 7 mg daily (13-17 years) | Lesser of 0.17 mg/kg or 4 mg daily (6-12 years) 7 mg daily (13-17 years) | Not a Schedule II medication. Sedation, somnolence, and fatigue are common and tend to decline over time. Consider baseline electrocardiogram (EKG) before starting. Tablets should not be crushed, chewed, or broken before swallowing because this will increase the rate of release. |
| KAPVAY® (clonidine ER) | 0.1 mg/day at bedtime | 0.4 mg/day in divided dose of 0.2 mg bid | 0.4 mg/day | Do not administer with high fat meals due to increased exposure. May not see effects for 4-6 weeks. Review personal and family cardiovascular history. Do not abruptly discontinue. Taper the daily dose of guanfacine ER by no more than 1 mg, and that of clonidine ER by no more than 0.1 mg every 3 to 7 days to avoid rebound hypertension. |
### ADHD Medications NOT FDA APPROVED in Children and Adolescents Ages 6 to 17 Years Old

<table>
<thead>
<tr>
<th>Generic Class/ Brand Name</th>
<th>Typical Starting Dose</th>
<th>Max Dose/Day</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha- adrenergic agonists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catapres® (clonidine)</td>
<td>0.05 mg nightly; titrate in 0.05 mg increments two times per day, three times per day, or four times per day.</td>
<td>27–40.5 kg: 0.2 mg; 40.5–45 kg: 0.3 mg; &gt;45 kg: 0.4 mg</td>
<td>The following applies to both alpha-2 adrenergic agonists: - May be used alone or as adjuvant to another medication class for ADHD. - Do not combine different alpha-2-adrenergic agents with each other - Effective for inattention, impulsivity and hyperactivity; modulating mood level; tics worsening from stimulants; sleep disturbances. Clonidine dosing is 1/10 guanfacine dosing. Clonidine and clonidine ER are more sedating than guanfacine preparations. Consider starting at bedtime to generate tolerance to sedating effects.</td>
</tr>
<tr>
<td>Tenex® (guanfacine)</td>
<td>0.5 mg nightly; titrate in 0.5 mg increments two times per day, three times per day, or four times per day.</td>
<td>27–40.5 kg: 2 mg; 40.5–45 kg: 3 mg; &gt;45 kg: 4 mg</td>
<td>May not see effects for 4-6 weeks. Review personal and family cardiovascular history. Consider pre-treatment EKG, if warranted by history. Taper the daily dose of guanfacine by no more than 1 mg every 3 to 7 days to avoid rebound hypertension.</td>
</tr>
</tbody>
</table>

*Note: Extended-release formulations of clonidine (Kapvay®) and guanfacine (Intuniv®) are FDA-approved ADHD medications in children and adolescents 6-17 years old, but short-acting formulations of clonidine (Catapres®) and guanfacine (Tenex®) are not FDA-approved for ADHD.

Continue titration until symptoms are adequately controlled, treatment-limiting side effects emerge, or maximum recommended daily dose is reached.
### Treatment of Anxiety Symptoms in the Context of ASD and ID

#### Level 0 - Comprehensive Assessment:
See *Principles of Practice*. In addition, give special consideration to:
- Developmental history and cognitive assessment (neuropsychological or educational)
- Anxiety symptom history in the child and family
- Parent and teacher rating scales (e.g., BASC)
- Comprehensive medical assessment (e.g., physical examination and relevant labs)

#### Level 1 - Psychosocial/non-pharmacological intervention and treatment of comorbidities:
- Address psychosocial and family stressors (e.g., domestic violence, parental substance misuse, family separation, bullying/school stressors)
- Treatment of comorbid medical problems (e.g., seizures, hyperthyroidism)
- Treatment of sleep problems
- Treatment of comorbid psychiatric illness
- Psychoeducation
- Behavioral therapy
- Speech and language therapy (Emphasize communication tools as communication difficulties are a contributing factor to anxiety).
- Cognitive behavioral therapy adapted for ASD and developmental level
- Social skills instruction

#### Level 2 - Sertraline, fluoxetine, or buspirone.
Although limited evidence exists for these medications for anxiety in children and adolescents with ASD, consider sertraline, fluoxetine, or buspirone. Refer to Table 8 on page 31 for dosing recommendations.

#### Level 3 - Reassess and consult specialist.
If symptoms persist, reassess child and consider a specialist consultation (referral to child and adolescent psychiatrist, pediatric neurologist, or developmental pediatrician).

### Not Recommended:
- Benzodiazepines
- Antipsychotics
## Treatment of Anxiety Symptoms in the Context of ASD and ID (continued)

### Table 8.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Starting Dose</th>
<th>Titration</th>
<th>Discontinuation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Pubertal Children</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sertraline</td>
<td>5 mg* once daily for two weeks</td>
<td>Increase by 5 mg every 2 weeks up to maximum daily dose of 100 mg/day</td>
<td>Depending on dose, taper safely.</td>
<td>Maximum dose of 100 mg per day; must monitor closely for activation.</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>2 mg* once daily for two weeks</td>
<td>Increase by 2 mg every two weeks up to maximum daily dose of 20 mg/day</td>
<td>Depending on dose, taper safely.</td>
<td>Maximum dose of 20 mg per day; this population is more prone to activation.</td>
</tr>
<tr>
<td>Buspirone</td>
<td>2.5 mg qam for one week</td>
<td>2.5 mg qam for 1 week, then 2.5 mg bid for one week, then increase by 2.5 mg per day every week as tolerated up to maximum dose of 15 mg twice per day</td>
<td>Depending on dose, taper safely.</td>
<td>Maximum dose of 15 mg twice per day (total dose 30 mg/day)</td>
</tr>
<tr>
<td><strong>Adolescents and Adults</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sertraline</td>
<td>12.5 mg once daily for two weeks</td>
<td>Increase by 12.5 mg to 25 mg every two weeks up to maximum daily dose of 200 mg/day</td>
<td>Depending on dose, taper safely.</td>
<td>Max dose of 200 mg daily; must monitor closely for activation.</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>5 mg once daily for two weeks</td>
<td>Increase by 5 mg every two weeks up to maximum daily dose of 40 mg/day</td>
<td>Depending on dose, taper safely.</td>
<td>Maximum dose of 40 mg per day; this population is more prone to activation.</td>
</tr>
<tr>
<td>Buspirone</td>
<td>2.5 mg bid for one week</td>
<td>2.5 mg twice per day for one week, then 4 mg twice per day for one week, then increase by 2.5 mg twice per day weekly up to a maximum dose of 20 mg twice per day</td>
<td>Depending on dose, taper safely.</td>
<td>Maximum dose of 20 mg twice per day (total dose 40 mg/day).</td>
</tr>
</tbody>
</table>

* Oral solution or liquid only

**Note:** Continue titration until symptoms are adequately controlled, treatment-limiting side effects emerge, or maximum recommended daily dose is reached.

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**Level 0 - Comprehensive Assessment:**
See *Principles of Practice.*

- Identify and treat any medical or psychosocial factors contributing to irritability prior to initiating medication:
  - Medical problems, such as constipation, headaches, infections, sleep
  - Changes in the environment, such as family stressors, trauma, or bullying
  - Side effects of psychotherapeutic or anticonvulsant medications (e.g., stimulants, levetiracetam)
  - Learned/reinforced behavioral patterns
  - Limited means of communication
- Detailed developmental and symptom history (Use of rating scales are highly recommended.)
- Physical examination
- If acute and indicated by history and physical examination, consider referral to appropriate specialist (e.g., neurology, endocrinology, gastroenterology, dentistry).
- EEG and/or brain imaging (CT or MRI), if clinically indicated
- Safety assessment (particularly in the presence of significant aggression/ self-injury)

---

**Level 1 - Psychosocial/non-pharmacological intervention and treatment of comorbidities:**
- Psychoeducation
- Behavior therapy [Applied Behavioral Analysis (ABA)]
- Speech and language therapy
- Occupational therapy
- Family therapy
- Parent-child therapy [Parent-Child Interaction Therapy (PCIT), Parent Management Therapy (PMT)]
- Social skills therapy
- Multi-systemic therapy (MST)
- Treatment of comorbid medical problems (if not already addressed)

---

**Level 2 Alpha-2 Agonist Monotherapy.**
Although limited evidence exists, consider an alpha-2 agonist (i.e., clonidine or guanfacine) for mild to moderate aggression.
Level 3 - Antipsychotic Monotherapy.

Consider risperidone or aripiprazole for severe irritability, including aggression, self-injury, and significant mood lability.

- If ASD, treatment with risperidone or aripiprazole is recommended. If monotherapy with one of these agents is ineffective, switch to the other agent.
- If ID, treatment with risperidone is recommended.

*Notes:* Aripiprazole is not well studied in ID population. Risperidone and aripiprazole are FDA-approved for treatment of irritability associated with autism in children and adolescents for the following ages: risperidone - ages 5-16; aripiprazole - ages 6-17. However, risperidone or aripiprazole are recommended after alpha-2 agonist monotherapy for mild to moderate irritability/aggression due to antipsychotic adverse effect risk profile.

Refer to Table 9 below for dosing recommendations.

Level 4 - Reassess and consult specialist (for both ASD and ID):

- If no response or treatment-limiting side effects emerge with risperidone and aripiprazole monotherapy, reassess and refer to a specialist (child and adolescent psychiatrist, pediatric neurologist, or developmental pediatrician).
- Consider use of alternative antipsychotics based on side-effect profiles and efficacy in small open-label studies (ziprasidone or low-dose loxapine).
- Consider addition of metformin if antipsychotic is very effective for reducing symptoms but causes significant weight gain (7% or more of body weight).

*Note:* Other antipsychotics have been less comprehensively studied. Use of antipsychotic medications may be associated with several side-effects (e.g., olanzapine and weight gain).

- Consider stopping the medication to evaluate need for continued use.
- Need to monitor for adverse metabolic effects. See Principles of Practice.

Table 9.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Starting Dose</th>
<th>Titration</th>
<th>Maximum Dose</th>
<th>Discontinuation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children over Age 6 and Adolescents</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risperidone (Risperdal®)</td>
<td>0.25 mg at bedtime</td>
<td>0.25 mg/week</td>
<td>Child (6-12): 2 mg Adolescent (13-17): 4 mg</td>
<td>0.25 mg-0.5 mg/3 days</td>
</tr>
<tr>
<td>Aripiprazole (Abilify®)</td>
<td>2 mg/day</td>
<td>2-2.5 mg/1-2 weeks</td>
<td>Child (6-12): 15 mg Adolescent (13-17): 15 mg</td>
<td>2.5 mg-5 mg/3 days</td>
</tr>
</tbody>
</table>
Children and adolescents with ASD and ID experience significant sleep disturbances that can lead to sleep deprivation for both the child and family. Underlying medical issues need to be identified.

**Level 0 - Comprehensive Assessment:**

See *Principles of Practice*. In addition, give special consideration to the following:

- **Screening** is best done by asking a short series of questions targeting insomnia using a screening tool (See Box 1 on page 7) and asking if the parent considers these a problem.
- **Primary sleep disorders** [Obstructive Sleep Apnea (OSA), Restless Leg Syndrome (RLS), Circadian Rhythm Disorders, and Narcolepsy]
- **Medical** [Gastroesophageal Reflux Disease (GERD), sleep apnea, night terrors, seizures, pain, low serum ferritin]; psychiatric (anxiety); and neurodevelopmental comorbidities.
- **Consider comorbid chronic sleep loss and primary sleep disorders as potential contributors to psychiatric symptoms.**
- **Concomitant medications, especially psychotropic medications (e.g., stimulants, SSRIs)**
- **Assessment of proper sleep hygiene/sleep practices:**
  - Poor sleep habits are a factor to consider when parents/children report inadequate sleep (e.g., bedtimes and wake up times that lack regular routine).
  - Electronics use, caffeine intake, napping
- **Caregiver role**
- **Presentation: sleep onset versus sleep maintenance**
Treatment of Sleep Disturbances in the Context of ASD and ID (continued)

Level 1 - Psychosocial/non-pharmacological intervention and treatment of comorbidities:

Education: Sleep toolkits are available for parents through Autism Speaks Autism Treatment Network (ATN). Visit floridamedicaidmentalhealth.org for updated links to sleep toolkits.

- Although the evidence base for effectiveness of behavioral interventions in children who have ASD & ID is limited, develop a sleep plan using specific behavioral interventions with the parents or caregivers to help address the identified sleep problems.

- Behavioral strategies:
  - Graduated extinction (e.g., withdrawal of reinforcement for inappropriate bedtime behaviors) and positive reinforcement of adaptive sleep behavior
  - Sleep training, bedtime fading, bedtime pass, and nightlight
  - Stimulus control, sleep restriction

- Caregiver-based interventions for younger children

- Healthy sleep practices for all

- Regular sleep schedule, avoid nighttime screens, limit caffeine, age appropriate napping

- Treat psychiatric comorbidities with appropriate psychotropic medications.
  - There should be agreement with the parents or caregivers about how symptoms and any emergent side effects of treatment will be measured, as well as the monitoring arrangements and expected duration of any trial of medication.

Level 2 - Melatonin.

- No data on children under 2 years old
- Dose: Starting dose 0.5 mg to 1 mg, titrate to 3 mg in children, and up to 10 mg in adolescents.
- Administer up to 2 hours prior to bedtime.
- Recommend the use of pharmaceutical grade melatonin
- Differences in response may occur due to lack of uniformity in manufacture of over-the-counter (OTC) brands.
- Better response if combined with behavioral interventions
- Most helpful for sleep onset; may not help for sleep maintenance
Level 3 - Clonidine.

- Pharmacotherapy should only be considered for short-term use if:
  - Insomnia results in significant impairments in child and/or caregiver daytime functioning.
  - Behavioral interventions alone are ineffective or if caregivers are unable to implement behavioral interventions.

- Pharmacotherapy with behavioral treatment may be appropriate for:
  - Short-term crisis intervention
  - Insomnia with comorbid high risk psychiatric (ADHD, MDD) or neurodevelopmental conditions (ASD)
  - Insomnia that exacerbates psychiatric and medical conditions

- Clonidine dose - 0.05 mg - 0.3 mg at bedtime:
  - Begin 0.05 mg to 0.1 mg at bedtime (0.1 mg tablet, ½ tablet to 1 tablet at bedtime).
  - If no significant improvement in sleep after one week, begin increasing by 0.05 mg to 0.1 mg each week (0.1 mg tablet, ½ tablet to 1 tablet each week) until there has been a satisfactory improvement in the sleep disturbance, treatment limiting side effects have emerged, or a total daily maximum dose of 0.3 mg at bedtime is reached.
  - Most helpful for sleep onset; may not help for sleep maintenance.
  - May develop tolerance and nocturnal awakening.
  - Monitor blood pressure and pulse.
  - Avoid abrupt discontinuation.

Level 4 - Consult specialist.

Consult with a specialist (pediatric sleep specialist, child and adolescent psychiatrist, pediatric neurologist, or developmental pediatrician).

Note: Antipsychotic medications, such as quetiapine (Seroquel®) should not be used for management of insomnia.

Not recommended:

- Medication as the first or sole treatment strategy.
- Use of sedating psychotherapeutic medication in the absence of other psychiatric disorder

The following have little or no scientific evidence, insufficient clinical pediatric use or experience and/or unacceptable risk/benefit ratios to warrant clinical recommendations:

- Amitriptyline, Benzodiazepines, Chloral Hydrate, Doxepin, Doxylamine, Eszopiclone, First/second generation antipsychotics (FGAs/SGAs), Ramelteon, Suvorexant, Zolpidem
Treatment of Restricted, Repetitive Behaviors in the Context of ASD and ID

Restricted, repetitive behaviors can include hand flapping, body rocking, repetition of sounds or words, arranging and re-arranging items, intense and unusual interests, strict adherence to routines, and difficulty tolerating change.

**GENERAL CONSIDERATIONS**

- Limited or no evidence exists for recommendation of psychotherapeutic medications in this domain.
- Restricted, repetitive behaviors should not be a target of treatment unless severely interfering with the individual’s level of functioning in daily activities or causing significant distress.
- Parent/family education is recommended.
- Caution is recommended when attempting to reduce these behaviors, as they may be helpful for self-regulation of anxiety, agitation, and/or frustration.
- In some cases, restricted interests can be an asset (e.g., if used as an effective reward for expected behaviors or a focus of social engagement).
- Cognitive Behavioral Therapy (CBT) and/or Applied Behavior Analysis (ABA) may be the most beneficial treatments and should be adapted to the individual’s language and cognitive abilities.

<table>
<thead>
<tr>
<th>Level 0 - Comprehensive Assessment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developmental history and cognitive assessment (neuropsychological or educational)</td>
</tr>
<tr>
<td>Restricted, repetitive behavior symptom history (simple versus complex, restricted interests), including assessment of severity and functional impairment</td>
</tr>
<tr>
<td>Comprehensive medical assessment, including physical examination (If history of staring spells or focal neurological signs, obtain EEG, MRI).</td>
</tr>
<tr>
<td>Parent-teacher rating scales</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level 1 - Psychosocial/non-pharmacological intervention and treatment of comorbidities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of comorbid medical problems, including seizures</td>
</tr>
<tr>
<td>Treatment of sleep problems</td>
</tr>
<tr>
<td>Treatment of comorbid psychiatric illness</td>
</tr>
<tr>
<td>Psychoeducation</td>
</tr>
<tr>
<td>Behavior strategies (e.g., structured activities, setting limits, redirection)</td>
</tr>
<tr>
<td>Behavior therapy (differential reinforcement of other behavior, extinction based therapy)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level 2 - CBT Adapted for ASD and/or ABA:</th>
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</thead>
<tbody>
<tr>
<td>CBT adapted for ASD and/or ABA</td>
</tr>
</tbody>
</table>

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Treatment of Depression or Bipolar Disorder Symptoms in the Context of ASD and ID

Identifying depression and/or mania/hypomania in individuals with ASD or ID can be challenging due to communication difficulties and difficulties identifying and expressing emotions. In patients with communication impairment, may need to rely on caregiver report.

- Inquire about symptoms of depression and/or mania/hypomania.
- Consider diagnosis if there is a change from baseline functioning (e.g., change in energy/activity level, sleep changes).
- Use family history to help evaluate risk.
- Cognitive behavioral therapy with a social skills component may be helpful.
Treatment of Catatonia in the Context of ASD and ID

- Catatonia may occur in up to 18% of adolescents and adults with ASD; symptoms may begin in childhood.
- Common features of catatonia in ASD (“autistic catatonia”) include: increased slowness, difficulty initiating movements, increased passivity, mutism, decreased oral intake, worsening of repetitive movement, and reversal of day and night.
- Assess for common causes of catatonia.
- Consult a specialist (e.g., child psychiatrist or neurologist) if catatonia is suspected.
- Catatonia may require inpatient medical and/or psychiatric hospitalization, especially if symptoms such as autonomic instability or dehydration are present.
- Under the care of a specialist, treat any identified underlying cause.
- Although evidence is limited, there is support for the use of high-dose lorazepam for treatment of catatonia in the context of ASD or ID. Electroconvulsive therapy (ECT) may be considered for cases refractory to treatment with a benzodiazepine, but no strong evidence in this population.
Treatment of Psychosis in the Context of ASD and ID

- Identification of psychotic symptoms in children with ASD and ID is challenging due to overlapping symptoms.
- Common features of psychosis in ASD include: decline from baseline functioning; presence of new onset delusions or hallucinations; change in intensity of magical thinking or blurring of reality/fantasy; and co-occurring change in mood. Change from usual functioning is key.
- Consult a child and adolescent psychiatrist if psychosis is suspected.
- Treatment guidelines for schizophrenia in children are available at floridamedicaidmentalhealth.org.

Please visit our website to view:

- Electronic versions of our adult and child/adolescent guidelines (available in full or in part)
- News and announcements
- Webinars
- Staff publications
- Alerts of recent publications and related literature
- Resources and tools
Principles of Practice Regarding the Use of Psychotherapeutic Medication in Children under Age 6

Level 0

Conduct comprehensive multi-informant, multi-modal, multi-disciplinary assessment for those with a positive screen. Rule out medical, social, and cognitive causes of behavioral symptoms. Use validated measures to assess and track psychiatric symptoms and impairment in young children.

Recommended measures of early childhood symptoms include:

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

Links to measures listed above are available at: floridamedicaidmentalhealth.org.

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.

Notes:

- Effort should be made to communicate between primary care providers, psychiatrists, caseworkers, and other team members to ensure integrated care.
- Prior to initiating any intervention (e.g., psychosocial, medication), assess and document the risks/benefits of treatment. Education of children should be age-appropriate and targeted to the condition.
- Children and parents/legal guardians should be educated about the risks and benefits of treatment, including review of boxed warnings.
- Written informed consent should be obtained from the parents/legal guardian (i.e., the individual legally able to consent to medical interventions) and documented in the chart.
Level 1
Start with evidence-based psychosocial treatment (e.g., parent training). Parental involvement is essential with involvement by other caregivers or school-based interventions as needed. Provide a comprehensive treatment plan to treat target symptoms and monitor treatment progress.
- Monitor response to treatment using reliable and valid measures of changes in the target symptoms.
- In mild cases, attempt a course of at least 12 weeks of psychosocial interventions before considering medication. Consider a trauma-informed treatment approach as appropriate.
- In moderate to severe cases, a higher level of intervention may be appropriate.
- Treatment should be individualized.

Level 2
If medications are being considered, first reassess the diagnosis and diagnostic formulation.
Weigh the risks and benefits of initiating treatment with psychotherapeutic medications. The long-term effects of antipsychotic medication use in children is not well studied.

If a decision is made to initiate medication:
- Initiate with monotherapy. Start low, go slow. Take into consideration the pharmacokinetics of the medication (i.e., absorption, distribution, metabolism, excretion).
- Except in rare cases, use monotherapy.
- Continue psychosocial treatment during treatment with medication.
- If possible, monitor effectiveness of interventions with pertinent rating scales.
- Use the lowest effective medication dose.
- Monitor for adverse effects of medications.
- After 6 to 9 months of stabilization, plan down titration trial (i.e., taper or discontinuation trial) to determine whether or not the medication is still needed and effective.
- 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.

Additional Considerations:
- Once medications are initiated, continue routine monitoring for medication benefits and side-effects.
- If medication is no longer beneficial, consider deprescribing (refer to deprescribing recommendations). Monitor for symptom exacerbation.
The use of antipsychotic medications in preschoolers (children under 6 years of age) is generally “off-label”, 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 children under age 6.

Before considering pharmacological treatment for children under age 6, the following guidelines are strongly recommended:

1. Patient has developmentally appropriate, comprehensive psychiatric assessment with diagnoses, impairments, treatment target and treatment plans clearly identified and documented.
2. Patient assessment must include evaluation of parental psychopathology and treatment needs, as well as family functioning.
3. Patient’s psychosocial treatments should precede the use of psychotherapeutic medications and should continue if medications are prescribed.

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

The dosing information is based on expert opinion and therefore is Level C evidence.

Table 10.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risperidone</td>
<td>Starting dose: 0.125 mg/day</td>
</tr>
<tr>
<td></td>
<td>Maximum dose: 1.5 mg/day</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>Starting dose: 1 mg/day</td>
</tr>
<tr>
<td></td>
<td>Maximum dose: 7.5 mg/day</td>
</tr>
</tbody>
</table>
Principles of Practice Regarding the Use of Psychotherapeutic Medications in Children Ages 6 to 17 Years Old

Level 0
Conduct comprehensive multi-informant, multi-modal, multi-disciplinary assessment for those with a positive screen. Rule out medical, social, and cognitive causes of behavioral symptoms.
Use validated measures to assess and track psychiatric symptoms and impairment in young children.

Recommended measures of symptoms in children and adolescents include:

- Ages 4–11 years: Strengths and Difficulties Questionnaire (SDQ)
- Ages 3–21 years: The Child/Adolescent Psychiatry Screen (CAPS)
- Ages 4–11 years: Home Situations Questionnaire (HSQ)

Links to measures listed above are available at: floridamedicaidmentalhealth.org.

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 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 history of abuse (physical, sexual) or neglect, traumatic life events, domestic violence, economic instability, etc.

Notes:
- Effort should be made to communicate between primary care providers, psychiatrists, caseworkers, and other team members to ensure integrated care.
- Prior to initiating any intervention (e.g., psychosocial, medication), assess the risks/benefits of treatment. Education of children should be age-appropriate and targeted to the condition.
- Children/adolescents and parents/legal guardians should be educated about the risks and benefits of treatment, including review of boxed warnings.
- Written informed consent should be obtained from the parents/legal guardian (i.e., the individual legally able to consent to medical interventions) and documented in the chart.
### Level 1
Start with psychosocial treatment. Parental involvement is essential, with involvement of other caregivers or school-based interventions as needed.

- Provide a comprehensive treatment plan to treat target symptoms and monitor treatment progress. Monitor response to treatment using reliable and valid measures of changes in the target symptoms.
- In mild cases, attempt a course of at least 12 weeks of psychosocial interventions before considering medication.
- In moderate to severe cases, a higher level of intervention may be appropriate as the initial step.

### Level 2
If medications are being considered, first reassess the diagnosis and diagnostic formulation. Weigh the risks and benefits of initiating treatment with psychotherapeutic medications.

**If a decision is made to initiate medication:**

- Initiate with monotherapy. Start low, go slow.
- Except in rare cases, use monotherapy.
- Continue psychosocial treatment during treatment with medication.
- Monitor for suicidality.
- Monitor for adverse effects of medications.
- The use of antipsychotics should be restricted to the diagnoses of schizophrenia (rare in children), mania/bipolar disorder, psychotic depression, drug induced psychosis, Tourette’s syndrome and tic disorders, and in some cases, severe aggression as a target symptom.
- On rare occasions, antipsychotics may be used in obsessive compulsive disorder (OCD) after extensive cognitive behavioral therapy (CBT) or failure of two adequate selective serotonin reuptake inhibitor (SSRI) trials.
- Antipsychotics should not be used primarily to target ADHD symptoms or as sedatives in children.
- There may be instances where antipsychotics are used for parasuicidal and severe self-injurious behaviors.

**Additional Considerations:**

- Once medications are initiated, continue routine monitoring for medication benefits and side-effects. For children on long-term, continuous antipsychotic use, at minimum, yearly re-assessment of medication benefits and side-effects is recommended.
- If medication is no longer beneficial, consider deprescribing (refer to deprescribing recommendations). Monitor for symptom exacerbation.
- Consider a trauma-informed treatment approach as appropriate.
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.

Provide accessible information to parents and families about identifying and managing side effects, including lifestyle and nutritional changes, monitoring labs, etc.

**Extrapyramidal Side Effects**
- Monitor for extrapyramidal side effects (EPS) associated with antipsychotic use. Scales for assessing for EPS:
  - The Abnormal Involuntary Movement Scale (AIMS)
  - The Extrapyramidal Symptom Rating Scale (ESRS)
  - Dyskinesia Identification System: Condensed User Scale (DISCUS)

Links to measures listed above are available at [floridamedicaidmentalhealth.org](http://floridamedicaidmentalhealth.org).

**Metabolic Syndrome, Prediabetes, and Type 2 Diabetes Mellitus**
- Monitor for metabolic syndrome, prediabetes, and Type 2 Diabetes Mellitus (DM) when prescribing atypical antipsychotics.
- Metabolic Syndrome Diagnosis:
  - **Children ≤10 years**
    - In children ≤10 years old, metabolic syndrome cannot be diagnosed because cut-offs for blood pressure, fasting blood sugar, triglycerides, and fasting lipids are not well defined.
    - Child is at risk for metabolic syndrome if child has central obesity (waist circumference is >90th percentile).
  - **Children/Adolescents >10 years**
    - Metabolic syndrome is present if the child has central obesity [waist circumference is >90th percentile for age (or adult cut-off if lower)] plus any two of the following four risk factors:
      - Blood pressure (BP): ≥130 millimeters of mercury (mmHg) systolic, ≥85 mmHg diastolic, or treatment of previously diagnosed hypertension
      - Fasting blood glucose >100 milligrams per deciliter (mg/dL)
      - Fasting triglycerides ≥150 mg/dL
      - HDL <40 mg/dL
  - Prediabetes Diagnosis:
    - Fasting glucose from 100-125 mg/dL
    - OR
    - Hemoglobin A1c between 5.7% and 6.4%
Monitor for prediabetes and Type 2 Diabetes Mellitus (DM) in all children <18 years who are overweight and have one or more of the following risk factors (refer to Box 2 below):

**Box 2.**

### American Diabetes Association Risk-Based Screening for Type 2 Diabetes or Prediabetes in Asymptomatic Children and Adolescents (<18 years) in a Clinical Setting

**Criteria:**
- Overweight (BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% of ideal for height [Level A evidence]

Plus one or more additional factors based on the strength of their association with diabetes as indicated by evidence grades:
- Maternal history of diabetes or gestational diabetes during the child’s gestation [Level A evidence]
- Family History of type 2 diabetes in first- or second-degree relative [Level A evidence]
- Race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander) [Level A evidence]
- Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, or small-for-gestational-age birth weight) [Level B evidence]

**Notes:**
- Overweight is defined as BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% of ideal for height.
- The American Diabetic Association recommends testing hemoglobin A1c every 3 years beginning at age 10 or onset of puberty in children who are overweight and have two or more risk factors for metabolic syndrome or Type 2 DM.
- For individuals receiving antipsychotic medications, the American Diabetic Association and American Psychiatric Association recommend metabolic monitoring as noted in Table 11 on page 48.
- If metabolic abnormalities are present, refer to the primary care physician for further evaluation/treatment and integrate care.
Table 11.

American Diabetes Association/American Psychiatric Association Guidelines for Metabolic Monitoring in Recipients of Antipsychotic Medications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Monitoring Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>Medical history*</td>
<td>X</td>
</tr>
<tr>
<td>Waist circumference</td>
<td>X</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>X</td>
</tr>
<tr>
<td>Fasting glucose or hemoglobin A1c</td>
<td>X</td>
</tr>
<tr>
<td>Fasting lipids (HDL, LDL, triglycerides, total cholesterol)</td>
<td>X</td>
</tr>
</tbody>
</table>

*Notes: Medical history includes personal and family history of obesity, diabetes, hypertension, and cardiovascular disease. More frequent assessments may be warranted based on clinical status.
Box 3.  

American Diabetes Association Criteria for Diagnosis of Diabetes

- Fasting plasma glucose (FPG) ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 hours.

OR

- 2 hour plasma glucose (PG) ≥200 mg/dL (11.1 mmol/L) during oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization (WHO), using a glucose load containing the equivalent of 75-grams anhydrous glucose dissolved in water.

OR

- Hemoglobin A1C ≥6.5% (48 mmol/mol).

Note: The test should be performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP) certified and standardized to the Diabetes Control and Complication Trial (DCCT) assay.

OR

- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).

Notes: In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing. The epidemiological studies that form the basis for recommending A1c to diagnose diabetes includes only adult populations.

ProLactin Monitoring

- There is a relationship between prolactin elevation and atypical antipsychotics. Although evidence does not support need for routine monitoring of prolactin levels in asymptomatic youths, surveillance for signs/symptoms of prolactin elevation (e.g., gynecomastia, galactorrhea, irregular menses) is recommended.

- When symptoms of elevated prolactin develop, consider decreasing the dose of the atypical antipsychotic, switching to a different atypical antipsychotic, or discontinuing medication.

For a full list of references, visit floridamedicaidmentalhealth.org.
<table>
<thead>
<tr>
<th>List of Abbreviations</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ABA:</strong> Applied Behavior Analysis</td>
<td></td>
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<tr>
<td><strong>ABC:</strong> Aberrant Behavior Checklist</td>
<td></td>
</tr>
<tr>
<td><strong>ADHD:</strong> Attention Deficit-Hyperactivity Disorder</td>
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</tr>
<tr>
<td><strong>ADI-R:</strong> Autism Diagnostic Interview—Revised</td>
<td></td>
</tr>
<tr>
<td><strong>ADOS-2:</strong> Autism Diagnostic Observation Schedule, Second Edition</td>
<td></td>
</tr>
<tr>
<td><strong>AIMS:</strong> Abnormal Involuntary Movement Scale</td>
<td></td>
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<tr>
<td><strong>ASD:</strong> Autism Spectrum Disorder</td>
<td></td>
</tr>
<tr>
<td><strong>ATN:</strong> Autism Speaks Autism Treatment Network</td>
<td></td>
</tr>
<tr>
<td><strong>BEARS:</strong> Bedtime problems; Excessive daytime sleepiness; Awakenings during the night; Regularity and duration of sleep; Snoring</td>
<td></td>
</tr>
<tr>
<td><strong>BID or bid:</strong> Latin abbreviation of “bis in die,” meaning two times daily</td>
<td></td>
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<tr>
<td><strong>BMI:</strong> Body mass index</td>
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<tr>
<td><strong>BP:</strong> Blood pressure</td>
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<tr>
<td><strong>CAPS:</strong> Child/Adolescent Psychiatry Screen</td>
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<tr>
<td><strong>CARD:</strong> Center for Autism and Related Disabilities</td>
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<tr>
<td><strong>CARS-2:</strong> Childhood Autism Rating Scale, Second Edition</td>
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<tr>
<td><strong>CAST:</strong> Childhood Autism Spectrum Test</td>
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<tr>
<td><strong>CBT:</strong> Cognitive Behavioral Therapy</td>
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<tr>
<td><strong>CDC:</strong> Centers for Disease Control and Prevention</td>
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<tr>
<td><strong>CSHQ:</strong> Children’s Sleep Habits Questionnaire</td>
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<tr>
<td><strong>DISCUS:</strong> Dyskinesia Identification System: Condensed User Scale</td>
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<tr>
<td><strong>DM:</strong> Diabetes Mellitus</td>
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<tr>
<td><strong>EEG:</strong> Electroencephalogram</td>
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<tr>
<td><strong>ECG:</strong> Electrocardiogram</td>
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<tr>
<td><strong>EPS:</strong> Extrapyramidal Symptoms</td>
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<tr>
<td><strong>ESRS:</strong> Extrapyramidal Symptom Rating Scale</td>
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<tr>
<td><strong>FND:</strong> Family Network on Disabilities</td>
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<tr>
<td><strong>HbA1c:</strong> Hemoglobin A1c</td>
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<tr>
<td><strong>HEAL:</strong> Healing Every Autistic Life</td>
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<tr>
<td><strong>HSQ:</strong> Home Situations Questionnaire</td>
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</tbody>
</table>
List of Abbreviations (continued)

**ID**: Intellectual Disability/Intellectual Developmental Disorder

**M-CHAT**: Modified Checklist for Autism in Toddlers

**mg**: milligrams

**mg/day**: milligrams per day

**mg/dL**: milligrams per deciliter

**mg/kg**: milligrams per kilogram

**mg/kg/day**: milligrams per kilograms per day

**MIND**: Medical Investigation of Neurodevelopmental Disorders

**mmHg**: millimeters of mercury

**MRI**: Magnetic Resonance Imaging

**NICHD**: National Institute of Child Health and Human Development

**NIMH**: National Institute of Mental Health

**OCD**: Obsessive-Compulsive Disorder

**ODT**: Orally Disintegrating Tablet

**PCIT**: Parent-Child Interaction Therapy

**PMT**: Parent Management Training

**SAS**: Simpson-Angus Scale

**SCQ**: Social Communication Questionnaire

**SDQ**: Strengths and Difficulties Questionnaire

**SSRI**: Selective Serotonin Reuptake Inhibitor

**SRS-2**: Social Responsiveness Scale, Second Edition

**TID or tid**: Latin abbreviation of “tier in die,” meaning three times daily

**QAM or qam**: every morning
Working with Medicaid health plans and providers to:

- Improve behavioral health prescribing practices
- Improve patient adherence to medication
- Reduce clinical risks and medication side effects
- Improve behavioral and physical health outcomes

The following treatment guidelines are available on our website at floridamedicaidmentalhealth.org.

- Best Practice Recommendations for Women of Reproductive Age with Severe Mental Illness and Comorbid Substance Use Disorders
- Best Practice Psychotherapeutic Medication Guidelines for Adults
- Monitoring Physical Health and Side-Effects of Psychotherapeutic Medications in Adults and Children: An Integrated Approach
- Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents
- Autism Spectrum Disorder & Intellectual Developmental Disorder: Best Practice Psychotherapeutic Medication Recommendations for Target Symptoms in Children and Adolescents

The Florida Pediatric Psychiatry Hotline is a free service that provides consultation about medication management.

Florida Pediatric Psychiatry Hotline
1-866-487-9507

For more information, visit us at floridamedicaidmentalhealth.org
References

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


References for Principles of Practice in the Context of ASD and ID:


References (continued)


References for Special Considerations in Children under Age 6:


References for Complementary and Alternative Treatments for Children with ASD:


References (continued)


Food and Drug Administration. FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy. 25 June 2018 [Date of access 3 Jan 2019]. Available at: https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm.


References for Use of Psychotherapeutic Medications in Children and Adolescents with ASD and ID:


References for Treatment of Hyperactive, Impulsive, and Inattentive Symptoms in the Context of ASD and ID:


References for Treatment of Anxiety Symptoms in the Context of ASD and ID:


References for Treatment of Aggression: Irritability, Self-Injury, Aggressive Behavior, and Explosive Outbursts in the Context of ASD and ID:


References (continued)


References for Treatment of Sleep Disturbances in the Context of ASD and ID:


References (continued)


Posey DJ, Guenin KD< Kohn AE, Swiezy NB and McDougle CJ. A naturalistic open-label study of mirtazapine in autistic and other pervasive developmental disorders. J Child Adolesc Psychopharmacol. 2011 Fall; 11(3) 267-77.


References (continued)


References for Treatment of Restricted, Repetitive Behaviors in the Context of ASD and ID:


References for Treatment of Depression or Bipolar Disorder Symptoms in the Context of ASD and ID:


References for Treatment of Catatonia in the Context of ASD and ID:

References for Treatment of Psychosis in the Context of ASD and ID:


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Electronic versions of our adult and child/adolescent guidelines
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News and announcements
Webinars
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Alerts of recent publications and related literature
Resources and tools

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