Developed by:

Texas Department of Family and Protective Services
and
The University of Texas at Austin College of Pharmacy

with review and input provided by:

- Federation of Texas Psychiatry
- Texas Pediatric Society
- Texas Academy of Family Physicians
- Texas Medical Association
  and
Rutgers University-Center for Education and Research on Mental Health Therapeutics

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Table of Contents

- Introduction and General Principles ................................................................. 3-6
- Criteria Indicating Need for Further Review of a Child's Clinical Status .......... 7
- Psychotropic Medication Tables ....................................................................... 8-17
- Glossary ............................................................................................................. 18
- References ...................................................................................................... 19-22
- Web Link References ....................................................................................... 23
- Members of the Ad Hoc Working Group .......................................................... 24
- Acknowledgements and Web Address for the Parameters Document ............ 25
The use of psychotropic medications by children and youth is an issue confronting parents, other caregivers, and health care professionals across the United States. Children and youth in foster care, in particular, have multiple needs, including those related to emotional or psychological stress. They typically have experienced abusive, neglectful, serial or chaotic caretaking environments. Birth family history is often not available. These children often present with a fluidity of different symptoms over time reflective of past traumatic events that may mimic many psychiatric disorders and result in difficulties with attachment, mood regulation, behavioral control, and other areas of functioning.

Because of the complex issues involved in the lives of foster children, it is important that a comprehensive evaluation be performed before beginning treatment for a mental or behavioral disorder. Except in urgent situations such as suicidality, psychosis, self-injurious behavior, physical aggression that is acutely dangerous to others, or severe impulsivity endangering the child or others; when there is marked disturbance of psychophysiological functioning (such as profound sleep disturbance), or when the child shows marked anxiety, isolation, or withdrawal. Given the history of trauma, unusual stress and change in environmental circumstances associated with being a child in foster care, psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication. Referral for trauma-informed, evidence-based psychotherapy should be considered when available and appropriate. Equally important, the role of the health care provider and the health care environment’s potential to exacerbate a child’s symptoms, given their respective trauma history, should be considered and minimized. Patient and caregiver education should be provided about the condition to be treated, treatment options (non-pharmacological and pharmacological), treatment expectations, and potential side effects that may occur during the prescription of psychotropic medications.

It is recognized that many psychotropic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. The FDA has a statutory mandate to determine whether pharmaceutical company sponsored research indicates that a medication is safe and effective for those indications that are listed in the approved product labeling. The FDA assures that information in the approved product labeling is accurate, and limits the manufacturer’s marketing to the information contained in the approved labeling. The FDA does not regulate physician and other health provider practice. In fact,
the FDA has stated that it does “not limit the manner in which a practitioner may prescribe an approved drug.” Studies and expert clinical experience often support the use of a medication for an “off-label” use. Physicians should utilize the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what is best for each individual patient. To that end, clear documentation of the physician’s rationale in the medical record facilitates continuity of care and minimizes misinterpretation.

**Role of Primary Care Providers**

Primary care providers play a valuable role in the care of youth with mental disorders. Not only are they the clinicians most likely to initially interact with children who are in distress due to an emotional or psychiatric disorder, but also an inadequate number of child psychiatrists are available to meet all children’s mental health needs. Primary care clinicians are in an excellent position to perform screenings of children for potential mental disorders, and they should be able to diagnose and treat relatively straightforward situations such as uncomplicated ADHD, anxiety, or depression. Primary care providers should provide advice to youth in foster care and their care givers about handling feelings and behaviors, recognizing the need for help, making decisions regarding healthy life styles, and the available treatments for childhood mental disorders. As always, consideration should be given regarding the need for referral for counseling, psychotherapy, or behavioral therapy. Primary care providers vary in their training, clinical experience, and confidence to address mental disorders in children. Short courses and intensive skills oriented seminars may be beneficial in assisting primary care clinicians in caring for children with mental disorders. Active liaisons with child psychiatrists who are available for phone consultation or referral can be beneficial in assisting primary care clinicians to meet the mental health needs of children. “The management of common presentations of ADHD, depression and anxiety, psychotherapy referral, psychopharmacology and appropriate child psychiatry referral are within the scope of general pediatric practice” (Southammakosane 2015). In addition, the American Academy of Pediatrics has recently provided a policy statement (“Health Care Issues for Children and Adolescents in Foster Care and Kinship Care”) which can be found at: [http://pediatrics.aappublications.org/content/136/4/e1131](http://pediatrics.aappublications.org/content/136/4/e1131)

**General principles regarding the use of psychotropic medications in children include:**

- A DSM-5 psychiatric diagnosis should be made before the prescribing of psychotropic medications.

- Clearly defined target symptoms and treatment goals for the use of psychotropic medications should be identified and documented in the medical record at the time of or before beginning treatment with a psychotropic medication. These target symptoms and treatment goals should be assessed at each clinic visit with the child and caregiver in a culturally and linguistically appropriate manner. Whenever possible, standardized clinical rating scales (clinician, patient, primary caregiver, teachers, and other care providers) or other measures should be used to quantify the response of the child's target symptoms to treatment and the progress made toward treatment goals.

- In making a decision regarding whether to prescribe a psychotropic medication in a specific child, the clinician should carefully consider potential side effects, including those that are uncommon but potentially severe, and evaluate the overall benefit to risk ratio of pharmacotherapy. Except in the case of an emergency, informed consent should be obtained from the appropriate party(s) before beginning psychotropic medication. Informed consent to treatment with psychotropic medication entails diagnosis, expected benefits and risks of treatment, including common side effects, discussion of laboratory findings, and uncommon but potentially severe adverse events. Alternative treatments, the risks associated with no treatment, and the overall potential benefit to risk ratio of treatment should be discussed.

- Whenever possible, trauma-informed, evidence-based psychotherapy, should begin before or concurrent with the prescription of psychotropic medication.

- Before starting psychopharmacological treatment in preschool-aged children even more emphasis should be placed on treatment with non-psychopharmacological interventions. Assessment of parent functioning and mental health needs, in addition to training parents in evidence-based behavior management can also reduce the need for the use of medication.

- Medication management should be collaborative. Youth, as well as caregivers, should be involved in decision-making about treatment, in accordance with their developmental level. Parents providing informed consent should be engaged, and where applicable, other caregivers, family, and child related agencies should be involved.

- During the prescription of psychotropic medication, the presence or absence of medication side effects should be documented in the child’s medical record at each visit.

- Appropriate monitoring of indices such as height, weight, blood pressure, or laboratory findings should be documented.

- Monotherapy regimens for a given disorder or specific target symptoms should usually be tried before polypharmacy regimens. While the goal is to use as few psychotropic medications as can be used to appropriately address the child’s clinical status, it is recognized that the presence of psychiatric comorbidities may affect the number of
psychotropic medications that are prescribed. When polypharmacy regimens are needed, addition of medications should occur in a systematic orderly process, accompanied by on-going monitoring, evaluation, and documentation. The goal remains to minimize polypharmacy while maximizing therapeutic outcomes.

- Medications should be initiated at the lower end of the recommended dose range and titrated carefully as needed.

- Only one medication should be changed at a time, unless a clinically appropriate reason to do otherwise is documented in the medical record. (Note: starting a new medication and beginning the dose taper of a current medication is considered one medication change).

- The use of “prn” or as needed prescriptions is discouraged. If they are used, the situation indicating need for the administration of a prn medication should be clearly indicated as well as the maximum dosage in a 24 hour period and in a week. The frequency of administration should be monitored to assure that these do not become regularly scheduled medications unless clinically indicated.

- The frequency of clinician follow-up should be appropriate for the severity of the child’s condition and adequate to monitor response to treatment, including: symptoms, behavior, function, and potential medication side effects. At a minimum, a child receiving psychotropic medication should be seen by the clinician at least once every ninety days.

- The potential for emergent suicidality should be carefully evaluated and monitored, particularly in depressed children and adolescents as well as those initiating antidepressants, those having a history of suicidal behavior or deliberate self-harm and those with a history of anxiety or substance abuse disorders.

- If the prescribing clinician is not a child psychiatrist, referral to or consultation with a child psychiatrist, or a general psychiatrist with significant experience in treating children, should occur if the child's clinical status has not shown meaningful improvement within a timeframe that is appropriate for the child's diagnosis and the medication regimen being used.

- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, appropriateness of medication daily dosage, accuracy of the diagnosis, the occurrence of comorbid disorders (including substance abuse and general medical disorders), and the influence of psychosocial stressors.

- If a medication has not resulted in improvement in a child's target symptoms (or rating scale score), discontinue that medication rather than adding a second medication to it.

- If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-5 non-psychotic diagnosis (e.g., conduct disorder, oppositional defiant disorder, intermittent explosive disorder), and the behavior disturbance has been in remission for six months, then serious consideration should be given to slow tapering and discontinuation of the medication. If the medication is continued in this situation, the necessity for continued treatment should be evaluated and documented in the medical record at a minimum of every six months.

- The clinician should clearly document care provided in the child’s medical record, including history, mental status assessment, physical findings (when relevant), impressions, rationale for medications prescribed, adequate laboratory monitoring specific to the drug(s) prescribed at intervals required specific to the prescribed drug and potential known risks, medication response, presence or absence of side effects, treatment plan, and intended use of prescribed medications.

Use of Psychotropic Medication in Preschool Age Children

The use of psychotropic medication in young children of preschool ages is a practice that is limited by the lack of evidence available for use of these agents in this age group. The Preschool Psychopharmacology Working Group (PPWG) published guidelines (Gleason 2007) summarizing available evidence for use of psychotropic medications in this age group. The PPWG was established in response to the clinical needs of preschoolers being treated with psychopharmacological agents and the absence of systematic practice guidelines for this age group, with its central purpose to attempt to promote an evidence-based, informed, and clinically sound approach when considering medications in preschool-aged children.

The PPWG guidelines emphasize consideration of multiple different factors when deciding on whether to prescribe psychotropic medications to preschool-aged children. Such factors include the assessment and diagnostic methods utilized in evaluating the child for psychiatric symptoms/illness, the current state of knowledge regarding the impact of psychotropic medication use on childhood neurodevelopmental processes, the regulatory and ethical contexts of use of psychotropic medications in small children (including available safety information and FDA status), and the existing evidence base for use of psychotropic medication in preschool aged children.

The publication includes specific guidelines and algorithm schematics developed by the PPWG to help guide treatment decisions for a number of psychiatric disorders that may present in preschool-aged children, including Attention-Deficit Hyperactivity Disorder, Disruptive Behavioral Disorders, Major Depressive Disorder, Bipolar Disorder, Anxiety Disorders, Post-Traumatic Stress Disorder, Obsessive-Compulsive Disorder, Pervasive Developmental...
Disorders, and Primary Sleep Disorders. The working group’s key points and guidelines are similar to the general principles regarding the use of psychotropic medication in children already detailed in this paper. However, the working group’s algorithms put more emphasis on treating preschool-aged children with non-psychopharmacological interventions (for up to 12 weeks) before starting psychopharmacological treatment, in an effort to be very cautious in introducing psychopharmacological interventions to rapidly developing preschoolers.

The working group also emphasizes the need to assess parent functioning and mental health needs, in addition to training parents in evidence-based behavior management, since parent behavior and functioning can have a large impact on behavior and symptoms in preschool-aged children.

**Distinguishing between Levels of Warnings Associated with Medication Adverse Effects**

Psychotropic medications have the potential for adverse effects, some that are treatment limiting. Some adverse effects are detected prior to marketing, and are included in the FDA approved product labeling provided by the manufacturers. When looking at product labeling, these adverse effects will be listed in the “Warnings and Precautions” section. As well, the “Adverse Reactions” section of the product labeling will outline those adverse effects reported during clinical trials, as well as those discovered during post-marketing evaluation. Many tertiary drug information resources also list common adverse effects and precautions for use with psychotropic medications.

At times, post-marketing evaluation may detect critical adverse effects associated with significant morbidity and mortality. The Food and Drug Administration (FDA) may require manufacturers to revise product labeling to indicate these critical adverse effects. If found to be particularly significant, these effects are demarcated by a box outlining the information at the very beginning of the product labeling, and have, in turn, been named boxed warnings. Boxed warnings are the strongest warning required by the FDA. It is important for clinicians to be familiar with all medication adverse effects, including boxed warnings, in order to appropriately monitor patients and minimize the risk of their occurrence. The medication tables include boxed warnings as well as other potential adverse effects. The list of potential adverse effects in the tables should not be considered exhaustive, and the clinician should consult the FDA approved product labeling and other reliable sources for information regarding medication adverse effects.

The FDA has in recent years taken additional measures to try to help patients avoid serious adverse events. New guides called Medication Guides have been developed, and are specific to particular medication and medication classes. Medication Guides advise patients and caregivers regarding possible adverse effects associated with classes of medications, and include precautions that they or healthcare providers may take while taking/prescribing certain classes of medications. The FDA requires that Medication Guides be issued with certain prescribed medications and biological products when the Agency determines that certain information is necessary to prevent serious adverse effects, that patient decision-making should be informed by information about a known serious side effect with a product, or when patient adherence to directions for the use of a product are essential to its effectiveness. During the drug distribution process, if a Medication Guide has been developed for a certain class of medications, then one must be provided with every new prescription and refill of that medication.

Copies of the Medication Guides for psychotropic medications can be accessed on the FDA website at: [http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm](http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm)

**Usual Recommended Doses of Common Psychotropic Medications**

The attached medication charts are intended to reflect usual doses and brief medication information for commonly used psychotropic medications. The tables contain two columns for maximum recommended doses in children and adolescents – the maximum recommended in the FDA approved product labeling, and the maximum recommended in medical and pharmacological literature sources. The preferred drug list of medications potentially prescribed for foster children is the same as for all other Texas Medicaid recipients.

The tables are intended to serve as a resource for clinicians. The tables are not intended to serve as comprehensive drug information references or a substitute for sound clinical judgment in the care of individual patients. Circumstances may dictate the need for the use of higher doses in specific patients. In these cases, careful documentation of the rationale for the higher dose should occur, and careful monitoring and documentation of response to treatment should be performed. If the use of higher medication doses does not result in improvement in the patient's clinical status within a reasonable time period (e.g., 2-4 weeks), then the dosage should be decreased and other treatment options considered.

Not all medications prescribed by clinicians for psychiatric diagnoses in children and adolescents are included in the following tables. However, in general, medications not listed do not have adequate efficacy and safety information available to support a usual maximum dose recommendation.

See Psychotropic Medication Tables beginning on page 8.
Criteria Indicating Need for Further Review of a Child’s Clinical Status

The following situations indicate a need for review of a patient’s clinical care. These parameters do not necessarily indicate that treatment is inappropriate, but they do indicate a need for further review.

For a child being prescribed a psychotropic medication, any of the following suggests the need for additional review of a patient’s clinical status:

1. Absence of a thorough assessment for the DSM-5 diagnosis(es) in the child’s medical record

2. Four (4) or more psychotropic medications prescribed concomitantly (side effect medications are not included in this count)

3. Prescribing of:
   - Two (2) or more concomitant stimulants *
   - Two (2) or more concomitant alpha agonists *
   - Two (2) or more concomitant antidepressants
   - Two (2) or more concomitant antipsychotics
   - Three (3) or more concomitant mood stabilizers

   * The prescription of a long-acting and an immediate-release stimulant or alpha agonist of the same chemical entity does not constitute concomitant prescribing.

Note: When switching psychotropics, medication overlaps and cross taper should occur in a timely fashion, generally within 4 weeks.

4. The prescribed psychotropic medication is not consistent with appropriate care for the patient’s diagnosed mental disorder or with documented target symptoms usually associated with a therapeutic response to the medication prescribed.

5. Psychotropic polypharmacy (2 or more medications) for a given mental disorder is prescribed before utilizing psychotropic monotherapy

6. The psychotropic medication dose exceeds usual recommended doses (literature based maximum dosages in these tables).

7. Psychotropic medications are prescribed for children of very young age, including children receiving the following medications with an age of:
   - Stimulants: Less than three (3) years of age
   - Alpha Agonists: Less than four (4) years of age
   - Antidepressants: Less than four (4) years of age
   - Mood Stabilizers: Less than four (4) years of age
   - Antipsychotics: Less than five (5) years of age

8. Prescribing by a primary care provider who has not documented previous specialty training for a diagnosis other than the following (unless recommended by a psychiatrist consultant):
   - Attention Deficit Hyperactive Disorder (ADHD)
   - Uncomplicated anxiety disorders
   - Uncomplicated depression

9. Antipsychotic medication(s) prescribed continuously without appropriate monitoring of glucose and lipids at least every 6 months.
### Stimulants for treatment of ADHD

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Patient Monitoring Parameters</th>
<th>Black Box Warning**</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine mixed salts*</td>
<td>Adderall®</td>
<td>Age 3-5 years: 2.5 mg/day</td>
<td>Age 3-5 years: 30 mg/day</td>
<td>Approved for children 3 years and older: 40 mg/day</td>
<td>One to three times daily</td>
<td>Baseline and ongoing: height, weight, heart rate, and blood pressure</td>
<td>Abuse potential</td>
<td>Risk of sudden death in those with pre-existing structural cardiac abnormalities or other serious heart problems</td>
</tr>
<tr>
<td></td>
<td>Evekeo®</td>
<td>Age 3-5 years: 5 mg/day</td>
<td>Age 6-12 years: &gt; 50 kg: 80 mg/day</td>
<td>Approved for children 6 years and older: 30 mg/day</td>
<td>Once daily</td>
<td>Baseline: Assessment using a targeted cardiac history of the child and the family, and a physical examination of the child with an EKG and/or a pediatric cardiology consult as indicated</td>
<td>Sudden death and serious cardiovascular events (Only boxed warning for amphetamine salts and dextroamphetamine)</td>
<td>Hypertension</td>
</tr>
<tr>
<td></td>
<td>Adderall®XR</td>
<td>Age 3-5 years: 5mg/day</td>
<td>Age 6-12 years: 12.5 mg/day</td>
<td>Approved for children 6 years and older:</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Age ≥ 13 years: 10 mg/day</td>
<td>Age 13-17 years: 12.5 mg/day</td>
<td>Ages 8-12 years: 18.8 mg/day</td>
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<tr>
<td>Amphetamine base</td>
<td>Adzenys®XR-ODT (oral disintegrating tablet)</td>
<td>Age ≥ 6 years: 6.3 mg/day (3.1 mg = 5 mg Adderall®XR)</td>
<td>Age ≥ 6 years: 20 mg/day</td>
<td>Approved for children 6 years and older: 20 mg/day</td>
<td>Once daily</td>
<td>Baseline and ongoing: height, weight, heart rate, and blood pressure</td>
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<tr>
<td></td>
<td>Dyanavel®XR (oral suspension)</td>
<td>Age ≥ 6 years: 2.5-5 mg/day (2.5 mg = 4 mg Adderall®XR)</td>
<td>Age ≥ 6 years: 20 mg/day</td>
<td>Approved for children 6 years and older: 20 mg/day</td>
<td>Once daily</td>
<td>Baseline: Assessment using a targeted cardiac history of the child and the family, and a physical examination of the child with an EKG and/or a pediatric cardiology consult as indicated</td>
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</tr>
<tr>
<td>Dextroamphetamine*</td>
<td>Dexedrine®</td>
<td>Age 3-5 years: 2.5 mg/day</td>
<td>Age 3-5 years: 30 mg/day</td>
<td>Approved for children 3 years and older: 40 mg/day</td>
<td>Once or twice daily</td>
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<tr>
<td></td>
<td>Zenzedi®</td>
<td>Age ≥ 6 years: 5 mg twice daily</td>
<td>Age ≥ 6 years: 30 mg/day</td>
<td>Approved for children 6 years and older: 40 mg/day</td>
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<td></td>
<td>Procentra® (oral suspension)</td>
<td></td>
<td>Age ≥ 6 years: &gt; 50 kg: 80 mg/day</td>
<td>Age ≥ 6 years: 40 mg/day</td>
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<td></td>
<td>Dexedrine Spansule®</td>
<td>Age 3-5 years: 5 mg/day</td>
<td>Age 3-5 years: 30 mg/day</td>
<td>Approved for children 3 years and older: 40 mg/day</td>
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<tr>
<td></td>
<td></td>
<td>Age ≥ 6 years: 5 mg/day</td>
<td>Age ≥ 6 years: 70 mg/day</td>
<td>Approved for children 6 years and older: 70 mg/day</td>
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<tr>
<td></td>
<td>Lisdenafetamine</td>
<td>Vyvanse®</td>
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<tr>
<td></td>
<td></td>
<td>Age 3-5 years: 10 mg/day</td>
<td>Age ≥ 6 years: 30 mg/day</td>
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<td></td>
<td></td>
<td>Age ≥ 6 years: 70 mg/day</td>
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</tbody>
</table>

* Generic available

** See the FDA approved product labeling for each medication for the full black box warnings.

+ XR, extended-release

(Continued on Page 9)
### Stimulants for treatment of ADHD (continued)

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)*</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Baseline/ Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylphenidate*</td>
<td>Ritalin®</td>
<td>• Age 3-5 years: 2.5 mg twice daily</td>
<td>Age 3-5 years: 20 mg/day</td>
<td>Approved for children 6 years and older:</td>
<td>One to three times daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(chewable and oral suspension)</td>
<td>• Age ≥ 6 years: 5 mg twice daily</td>
<td>Age ≥ 6 years:</td>
<td>Approved for children 6 years and older: 60 mg/day</td>
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<tr>
<td></td>
<td>MethylIN®SR</td>
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<tr>
<td></td>
<td>MethylIN®ER</td>
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<tr>
<td></td>
<td>Metadate®ER</td>
<td>• Age 3-5 years: 10 mg/day</td>
<td>Age 3-5 years: 10 mg/day</td>
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<td>See above</td>
<td>See above</td>
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<tr>
<td></td>
<td>Ritalin®LA</td>
<td></td>
<td>Age ≥ 6 years:</td>
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<tr>
<td></td>
<td>Metadate®CD</td>
<td>• Age 3-5 years: 10 mg/day</td>
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<tr>
<td></td>
<td>Quillivant®XR (oral suspension)</td>
<td>• Age ≥ 6 years: 10-20 mg/day</td>
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<td></td>
<td>QuillChew®ER (chewable)</td>
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<td></td>
<td>Aptensio®XR</td>
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<tr>
<td></td>
<td>Concerta®</td>
<td>Age ≥ 3 years: 18 mg/day</td>
<td>Age 3-5 years: 36 mg</td>
<td>Approved for children 6 years and older:</td>
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<tr>
<td></td>
<td></td>
<td>Age ≥ 6 years: 108 mg/day</td>
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<td>• Age 6-12 years: 54 mg/day</td>
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<td></td>
<td>• Age 13-17 years: lesser of 72 mg/day or 2 mg/kg/day, whichever is less</td>
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<tr>
<td></td>
<td>Daytrana®TD patch +</td>
<td>Age ≥ 3 years: 10 mg/day</td>
<td>Age 3-5 years: 20 mg</td>
<td>Approved for children 6 years and older:</td>
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<tr>
<td></td>
<td></td>
<td>Age ≥ 6 years: 30 mg/day</td>
<td>Age ≥ 6 years:</td>
<td>Approved for children 6 years and older: 30 mg/day</td>
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<tr>
<td></td>
<td>Dexmethylphenidate*</td>
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<tr>
<td></td>
<td>Focalin®</td>
<td>• Age 3-5 years: 2.5 mg twice daily</td>
<td>Age 3-5 years: 10 mg/day</td>
<td>Approved for children 6 years and older:</td>
<td>Twice daily</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Age ≥ 6 years: 2.5 mg twice daily</td>
<td>Age ≥ 6 years: 50 mg/day</td>
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</tr>
<tr>
<td></td>
<td>Focalin®XR</td>
<td>• Age 3-5 years: 5 mg/day</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Age ≥ 6 years: 5-10 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Generic available

** See the FDA approved product labeling for each medication for the full black box warnings.

+ IR, immediate release; SR, sustained-release formulation; CD, combined immediate release and extended release; ER and XR, extended-release; LA, long-acting; TD, transdermal

+ Daytrana®TD patch: Post marketing reports of acquired skin depigmentation or hypopigmentation of the skin
### Other ADHD Treatments

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)*</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Baseline/ Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin</td>
<td>Strattera®</td>
<td>- Age ≥ 6 years and weight ≤70 kg: 0.5 mg/kg/day &lt;br&gt; - Age ≥ 6 years and weight &gt;70 kg: 40 mg/day</td>
<td>Age ≥ 6 years: 1.8 mg/kg/day or 100 mg/day, whichever is less</td>
<td>Approved for treatment of ADHD (age 6-17 years): 1.4 mg/kg/day or 100 mg/day, whichever is less</td>
<td>Once or twice daily</td>
<td>• Baseline and ongoing: height, weight, heart rate, and blood pressure &lt;br&gt; • Onset of therapeutic effect typically delayed 3 weeks</td>
<td>Suicidal ideation in children and adolescents being treated for ADHD</td>
<td>• Severe liver injury &lt;br&gt; • Contraindicated to use within 14 days of an MAOI &lt;br&gt; • Increased blood pressure and heart rate &lt;br&gt; • Psychiatric adverse events &lt;br&gt; • Priapism (rare)</td>
</tr>
<tr>
<td>Catapres® (IR)</td>
<td>Clonidine*</td>
<td>- Age ≥ 6 years and weight ≤45 kg: 0.05 mg/day &lt;br&gt; - Age ≥ 6 years and weight &gt;45 kg: 0.1 mg/day</td>
<td>Age ≥ 6 years AND &lt;br&gt; - Weight 27-40.5 kg: 2 mg/day &lt;br&gt; - Weight 40.5-45 kg: 3 mg/day &lt;br&gt; - Weight &gt;45 kg: 4 mg/day</td>
<td>Not approved for treatment of ADHD in children and adolescents</td>
<td>One to four times daily</td>
<td>• Baseline and ongoing: heart rate and blood pressure &lt;br&gt; • Personal and family cardiovascular history</td>
<td>None</td>
<td>• Hypotension &lt;br&gt; • Bradycardia &lt;br&gt; • Syncope &lt;br&gt; • Sedation/Somnolence &lt;br&gt; • Taper, do not discontinue abruptly</td>
</tr>
<tr>
<td>Pamelor®</td>
<td>Aventyl®</td>
<td>Age ≥ 6 years: 1 mg/day</td>
<td>Age ≥ 6 years: 7 mg/day</td>
<td>Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD (age 6-17 years): 4 mg/day</td>
<td>Once daily</td>
<td>• Baseline and ongoing: heart rate and blood pressure &lt;br&gt; • Personal and family cardiovascular history</td>
<td>None</td>
<td>CAUTION IF USED WITH ANTIPSYCHOTICS (†, BP)</td>
</tr>
<tr>
<td>Tenex® (IR)</td>
<td>Imipramine*</td>
<td>- Age ≥ 6 years and weight ≤45 kg: 0.5 mg/kg/day &lt;br&gt; - Age ≥ 6 years and weight &gt;45 kg: 1 mg/day</td>
<td>Age ≥ 6-12 years: 4 mg/day &lt;br&gt; Age 13-17 years: 7 mg/day</td>
<td>Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD &lt;br&gt; - Age 6-12 years: 4 mg/day &lt;br&gt; - Age 13-17 years: 7 mg/day</td>
<td>Once daily</td>
<td>• Blood pressure and Pulse &lt;br&gt; • Mental status exam and suicide assessment</td>
<td>Increased risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders</td>
<td>• Lowers seizure threshold (use caution with other agents that may lower seizure threshold-e.g. antipsychotics, TCA's, excessive alcohol) &lt;br&gt; • Discontinuation syndrome &lt;br&gt; • Activation of mania/ hypomania &lt;br&gt; • Suicidal ideation &lt;br&gt; • Contraindicated for use within 14 days of an MAOI</td>
</tr>
<tr>
<td>Wellbutrin®</td>
<td>Buproprion*</td>
<td>Age ≥ 6 years: 3 mg/kg/day or 150 mg/day, whichever is less</td>
<td>Age ≥ 6 years: 6 mg/kg/day or 300 mg/day with no single dose &gt;150 mg, whichever is less</td>
<td>Not approved for children and adolescents</td>
<td>One to three times daily</td>
<td>• CBC &lt;br&gt; • Blood pressure and Pulse &lt;br&gt; • EKG &lt;br&gt; • Mental status exam and suicide assessment</td>
<td>• Caution with cardiac disease &lt;br&gt; • Cardiac conduction abnormalities &lt;br&gt; • Orthostatic hypotension &lt;br&gt; • Activation of mania/hypomania &lt;br&gt; • Anticholinergic and cognitive adverse effects &lt;br&gt; • Lowers seizure threshold &lt;br&gt; • Discontinuation syndrome &lt;br&gt; • Suicidal ideation &lt;br&gt; • Contraindicated for use within 14 days of an MAOI &lt;br&gt; • Use caution in those with history of suicide attempts; may be cardiotoxic in overdose</td>
<td></td>
</tr>
<tr>
<td>Wellbutrin®SR</td>
<td>Tofranil®</td>
<td>Same as above</td>
<td>400 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>Once or twice daily</td>
<td>Increased risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders</td>
<td>None</td>
<td>• CBC &lt;br&gt; • Blood pressure and Pulse &lt;br&gt; • EKG &lt;br&gt; • Mental status exam and suicide assessment</td>
</tr>
<tr>
<td>Wellbutrin®XL</td>
<td>Nortriptyline*</td>
<td>Same as above</td>
<td>450 mg/day</td>
<td>Approved for treatment of depression ≥ 12 years: 100 mg/day</td>
<td>Once daily</td>
<td>• CBC &lt;br&gt; • Blood pressure and Pulse &lt;br&gt; • EKG &lt;br&gt; • Mental status exam and suicide assessment</td>
<td>• Contraindicated for use within 14 days of an MAOI &lt;br&gt; • Use caution in those with history of suicide attempts; may be cardiotoxic in overdose</td>
<td></td>
</tr>
</tbody>
</table>

* Generic available  
+ IR, immediate release; SR, sustained-release formulation; ER, extended-release; XL, extended-length

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**Psychotropic Medication Utilization Parameters**

**Catapres® (IR)**

**Kapvay® (ER)**

**Tenex® (IR)**

**Intuniv® (ER)**

**Wellbutrin®**

**Buproprion* (brand)**

**Imipramine* (brand)**

**Nortriptyline* (brand)**

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**Literature Based Dosage**

**FDA Approved Dosage for Children and Adolescents**

**Schedule**

**Baseline/ Monitoring**

**Black Box Warning**

**Warnings and Precautions**

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**Generic available**

**IR, immediate release; SR, sustained-release formulation; ER, extended-release; XL, extended-length**

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**March 2016**

**(Tables Updated July 2016)**
# Antidepressants, SSRIs

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)+</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Patient Monitoring Parameters</th>
<th>Black Box Warning**</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citalopram*</td>
<td>Celexa®</td>
<td>• Age 6-11 years: 10 mg/day&lt;br&gt;• Age ≥ 12 years: 20 mg/day</td>
<td>• Age ≥ 6 years: 40 mg/day</td>
<td>Not approved for children and adolescents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Escitalopram*</td>
<td>Lexapro®</td>
<td>• Age 6-11 years: 5 mg/day&lt;br&gt;• Age ≥ 12 years (MDD): 10 mg/day</td>
<td>• Age 6-11 years: 20 mg/day&lt;br&gt;• Age ≥ 12 years: 30 mg/day</td>
<td>• Not approved for children&lt;br&gt;• Approved for treatment of MDD in adolescents (age 12-17 years): 20 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoxetine*</td>
<td>Prozac®</td>
<td>• Age 6-11 years: 5-10 mg/day&lt;br&gt;• Age ≥ 12 years: 10 mg/day</td>
<td>• Age ≥ 6 years: 60 mg/day</td>
<td>• Approved for treatment of MDD (age 6-18 years): 20 mg/day&lt;br&gt;• Approved for treatment of OCD (age 7-17 years): 60 mg/day</td>
<td>Once daily</td>
<td></td>
<td></td>
<td>Increased risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders</td>
</tr>
<tr>
<td>Paroxetine*</td>
<td>Paxil®</td>
<td>• Children: Not recommended&lt;br&gt;• Age ≥ 12 years: 10 mg</td>
<td>• Children: Not recommended&lt;br&gt;• Age ≥ 12 years: 40 mg</td>
<td>Not approved for children and adolescents</td>
<td></td>
<td></td>
<td></td>
<td>• Suicidal ideation&lt;br&gt;• Activation of mania/hypomania&lt;br&gt;• QTc prolongation potential (citalopram, fluoxetine, possibly escitalopram)</td>
</tr>
<tr>
<td>Paxil®CR</td>
<td></td>
<td>• Children: Not recommended&lt;br&gt;• Age ≥ 12 years: 25 mg</td>
<td>• Children: Not recommended&lt;br&gt;• Age ≥ 12 years: 50 mg</td>
<td>Not approved for children and adolescents</td>
<td></td>
<td></td>
<td></td>
<td>• Discontinuation syndrome&lt;br&gt;• Abnormal bleeding&lt;br&gt;• Contraindicated to use within 14 days of an MAOI; for fluoxetine, do not start MAOI for 5 weeks after fluoxetine discontinuation&lt;br&gt;• Serotonin Syndrome&lt;br&gt;• Hyponatremia risk</td>
</tr>
<tr>
<td>Fluvoxamine*</td>
<td>Luvox®</td>
<td>Age ≥ 8 years: 25 mg/day</td>
<td>• Age 8-11 years: 200 mg/day&lt;br&gt;• Age 12-17 years: 300 mg/day</td>
<td>Approved for treatment of OCD (age 8-17 years):&lt;br&gt;• Ages 8-11 years: 200 mg/day&lt;br&gt;• Ages 12-17 years: 300 mg/day</td>
<td>Daily doses &gt;50 mg should be divided</td>
<td></td>
<td></td>
<td>Serotonin Syndrome&lt;br&gt;• Hyponatremia risk</td>
</tr>
<tr>
<td>LuvooXR</td>
<td></td>
<td>Age ≥ 8 years: 100 mg/day</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Sertraline*</td>
<td>Zoloft®</td>
<td>• Age 6-12 years: 12.5-25 mg/day&lt;br&gt;• Age 13-17 years: 25-50 mg/day</td>
<td>• Age ≥ 6 years: 200 mg/day</td>
<td>Approved for treatment of OCD (age 6-17 years): 200 mg/day</td>
<td>Once daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vilazodone</td>
<td>Vibryd®</td>
<td>Insufficient Evidence</td>
<td>Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td>Insufficient Evidence</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Generic available

+ CR, controlled-release

** From Boxed Warning in FDA approved labeling for Antidepressants (SSRIs, SNRIs and Other Mechanisms): Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Both patients and families should be encouraged to contact the clinician if depression worsens, the patient demonstrates suicidal behavior or verbalizations, or if medication side effects occur. The appropriate utilization of non-physician clinical personnel who are knowledgeable of the patient population can aid in increasing the frequency of contact between the clinic and the patient/parent.

March 2016
(Tables Updated July 2016)
<table>
<thead>
<tr>
<th>Drug (generic)</th>
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<th>Schedule</th>
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<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venlafaxine*</td>
<td>Effexor®</td>
<td>Age 7-17 years: 37.5 mg/day</td>
<td>• Age 7-11 years: 150 mg/day • Age 12-17 years: 375 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>IR: Two to three times daily XR: Once daily</td>
<td>• Pregnancy test – as clinically indicated</td>
<td>Increased risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders</td>
<td>• Suicidal ideation • Abnormal bleeding • Severe skin reactions • Discontinuation syndrome • Activation of mania/hypomania • Hepatotoxicity • Elevated blood pressure and pulse • Serotonin Syndrome • Seizures • Hyponatremia • Contraindicated for use within 14 days of an MAOI</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>Cymbalta®</td>
<td>Age 7-17 years: 30 mg/day</td>
<td>Age 7-17 years: 120 mg/day</td>
<td>Approved for treatment of Generalized Anxiety Disorder Age 7-17 years: 120 mg/day</td>
<td>Once or twice daily</td>
<td>• Monitor for emergence of suicidal ideation or behavior • Blood pressure during dosage titration and as clinically indicated • Monitor weight and growth • Hepatic function testing – baseline and as clinically indicated • CBC and EKG at baseline and as clinically indicated for Clomipramine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desvenlafaxine</td>
<td>Pristiq®</td>
<td>• Children: Insufficient Evidence • Age 12-17 years: 50 mg/day</td>
<td>• Children: Insufficient Evidence • Age 12-17 years: 100 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>Once daily</td>
<td>• Monitoring for suicidal ideation or behavior • Blood pressure during dosage titration and as clinically indicated • Monitor weight and growth • Hepatic function testing – baseline and as clinically indicated • CBC and EKG at baseline and as clinically indicated for Clomipramine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levomilnacipram</td>
<td>Fetzima®</td>
<td>Insufficient Evidence</td>
<td>Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td>Insufficient Evidence</td>
<td>• Pregnancy test – as clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clomipramine*</td>
<td>Anafranil®</td>
<td>Age 10-17 years: 25 mg/day</td>
<td>Age 10-17 years: 3 mg/kg/day or 200 mg/day, whichever is less</td>
<td>Approved for treatment of OCD: Age 10-17 years: 3 mg/kg/day or 200 mg/day, whichever is less</td>
<td>Once daily</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**Antidepressants, SNRIs**

<table>
<thead>
<tr>
<th>Drug (generic)</th>
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<th>Schedule</th>
<th>Patient Monitoring Parameters</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mirtazapine*</td>
<td>Remeron®</td>
<td>Age ≥ 3 years: 7.5 mg/day</td>
<td>Age ≥ 3 years: 45 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>Once daily</td>
<td>• Pregnancy test – as clinically indicated • Monitor for emergence of suicidal ideation or behavior • Blood pressure during dosage titration and as clinically indicated • Monitor weight and height • Serum cholesterol levels • CBC baseline and periodically</td>
<td>Increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders</td>
<td>• Suicidal ideation • Abnormal bleeding • Weight gain • Discontinuation syndrome • Activation of mania/hypomania • Orthostatic hypotension and syncope • Serotonin Syndrome • Hyponatremia • Contraindicated for use within 14 days of an MAOI In addition: Hepatotoxicity, Seizures, and Neutropenia Potential with Mirtazapine</td>
</tr>
<tr>
<td>Vortioxetine</td>
<td>Trintellix®</td>
<td>Insufficient Evidence</td>
<td>Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td>Insufficient Evidence</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Generic Available
+ XR, extended-release

March 2016
(Tables Updated July 2016)
### Antipsychotics: Second Generation (Atypical)

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)*</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Patient Monitoring Parameters</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abilify®</td>
<td>Abilify®</td>
<td>Age ≥ 4 years: 2 mg/day</td>
<td>• Age 4-11 years: 15 mg/day</td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes (age 10-17 years) and Schizophrenia (13-17 years): 30 mg/day</td>
<td>Once daily</td>
<td>• Fasting plasma glucose level or hemoglobin A1C – at baseline, at 3 months, then every 6 months.</td>
<td>Increased the risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Discmetric® (oral disintegrating tab)</td>
<td>Age 5-9 years: 12.5-25 mg/day</td>
<td>• Age 5-9 years: 40mg/day</td>
<td>• Approved for treatment of irritability associated with Autistic Disorder (age 6-17 years): 15 mg/day</td>
<td>IR: One to three times daily</td>
<td>CBC as clinically indicated.</td>
<td>None related to youth</td>
<td>Extra pyramidal side effects</td>
</tr>
<tr>
<td></td>
<td>Abilify® (oral solution)</td>
<td>Age 10-17 years: 50 mg/day</td>
<td>• Age 10-17 years: 800 mg/day</td>
<td>• Approved for treatment of Schizophrenia (13-17 years): 800 mg/day</td>
<td>XR: Once daily</td>
<td>Pregnancy test – as clinically indicated.</td>
<td>None related to youth</td>
<td>Neuroleptic Malignant Syndrome</td>
</tr>
<tr>
<td>Quetiapine®</td>
<td>Seroquel®</td>
<td>Age 5-9 years: 12.5-25 mg/day</td>
<td>• Age 5-9 years: 40mg/day</td>
<td>• Approved for treatment of Bipolar Mania (age 10-17 years): 600 mg/day</td>
<td>IR: One to three times daily</td>
<td>• Blood pressure, pulse rate, height, weight and BMI measurement – at every visit</td>
<td>None related to youth</td>
<td>Tardive Dyskinesia</td>
</tr>
<tr>
<td></td>
<td>Seroquel®XR (brand only)</td>
<td>Age 10-17 years: 50 mg/day</td>
<td>• Age 10-17 years: 800 mg/day</td>
<td>• Approved for treatment of Schizophrenia (13-17 years): 800 mg/day</td>
<td>XR: Once daily</td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>Hyperglycemia and Diabetes Mellitus</td>
</tr>
<tr>
<td>Olanzapine®</td>
<td>Zyproxa®</td>
<td>Age ≥ 4 years: 1.25 mg/day</td>
<td>• Age 4-6 years: 12.5 mg/day</td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 20 mg/day</td>
<td>Once daily</td>
<td>• Sexual function– inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbances in males (Praspm has been reported with paliperidone, risperidone and ziprasidone). This inquiry should be done at each visit for the first 12 months and every 6 months thereafter.</td>
<td>None related to youth</td>
<td>Prolactinemia and gynecomastia (most common with risperidone and paliperidone)</td>
</tr>
<tr>
<td></td>
<td>Zyproxa Zydos®</td>
<td>Age ≥ 5 years: 2.5 mg/day</td>
<td>• Age 6-7 years: 20 mg/day</td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 20 mg/day</td>
<td>Once daily</td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>Orthostatic Hypotension</td>
</tr>
<tr>
<td>Risperidone®</td>
<td>Risperdal®</td>
<td>Age ≥ 6 years: 0.5 mg/day</td>
<td>• Age ≥ 6 years: 12.5 mg/day</td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 20 mg/day</td>
<td>Once or twice daily</td>
<td>• Risk of life threatening agranulocytosis</td>
<td>None related to youth</td>
<td>Leukopenia, neutropenia, and agranulocytosis</td>
</tr>
<tr>
<td></td>
<td>Risperdal® M-Tab® (oral disintegrating tablet)</td>
<td>Age ≥ 6 years: 20 mg/day</td>
<td>• Age ≥ 6 years: 60 mg/day</td>
<td>• Approved for treatment of irritability associated with autistic disorder (age 5-16 years): 3 mg/day</td>
<td>Once or twice daily</td>
<td>• Weight gain</td>
<td>None related to youth</td>
<td>Lowsers seizure threshold</td>
</tr>
<tr>
<td></td>
<td>Risperdal® (oral solution)</td>
<td>Age ≥ 6 years: 0.5 mg/day</td>
<td>• Age ≥ 6 years: 12.5 mg/day</td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 20 mg/day</td>
<td>Once or twice daily</td>
<td>• Dystonia</td>
<td>None related to youth</td>
<td>Cognitive and motor impairment potential</td>
</tr>
<tr>
<td>Clozapine®</td>
<td>Clozaril®</td>
<td>Age 8-11 years: 6.25-12.5 mg/day</td>
<td>• Age 8-11 years: 150-300 mg/day</td>
<td>• Target serum clozapine level of 350 ng/mL for optimal efficacy</td>
<td>Not approved for children and adolescents</td>
<td>• Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision-yearly.</td>
<td>None related to youth</td>
<td>Hyperthermia</td>
</tr>
<tr>
<td></td>
<td>FazaClo® (oral disintegrating tablet)</td>
<td>Age ≥ 12 years: 6.25-25 mg/day</td>
<td>• Age ≥ 12 years: 600 mg/day</td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 50 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>Extrapyramidal side effects</td>
</tr>
<tr>
<td></td>
<td>Versaclo® oral suspension</td>
<td>Age ≥ 12 years: 0.5 mg/day</td>
<td>• Age ≥ 12 years: 12.5 mg/day</td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 50 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>Olanzapine® can cause a rare but serious skin reaction known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms). Presence of a fever with a rash and swollen lymph glands, or swelling to the face requires immediate medical attention.</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>Abilify®</td>
<td>Age ≥ 10 years: 2.5 mg twice daily</td>
<td>• Age ≥ 10 years: 10 mg twice daily</td>
<td>• Approved for acute treatment of Bipolar Mania and Mixed Episodes (age 10-17 years): 10 mg twice daily</td>
<td>Twice daily, Avoid eating or drinking for 10 minutes after sublingual administration</td>
<td>• Risk of life threatening agranulocytosis</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td></td>
<td>Fanapt®</td>
<td>Insufficient Evidence</td>
<td>Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td>Insufficient Evidence</td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Paliperidone*</td>
<td>Invega®</td>
<td>Children: Insufficient Evidence</td>
<td>• Children: Insufficient Evidence</td>
<td>• Approved for treatment of Schizophrenia (age 12-17 years):</td>
<td>Once daily</td>
<td>• EKG - Baseline and as clinically indicated.</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adolescents: (Age ≥ 12 years): 3 mg/day</td>
<td>• Adolescents: Insufficient Evidence</td>
<td>• Weight ≤ 51 kg: 6 mg/day</td>
<td></td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Ziprasidone*</td>
<td>Geodon®</td>
<td>Bipolar Disorder (age 10-17 years)</td>
<td>• Bipolar Disorder (age 10-17 years): 0 ≤ S ≤ 45 kg: 80 mg/day</td>
<td>• Approved for treatment of Schizophrenia (age 12-17 years): 150 mg/day</td>
<td>Twice daily; take with ≥500 calorie meal</td>
<td></td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tourette’s Disorder: 5 mg/day</td>
<td>• Tourette’s Disorder: 5 mg/day</td>
<td>• Weight ≤ 45 kg: 150 mg/day</td>
<td></td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Lurasidone*</td>
<td>Latuda®</td>
<td>Insufficient Evidence</td>
<td>Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td>Insufficient Evidence</td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Brexpiprazole*</td>
<td>Rexulti®</td>
<td>Insufficient Evidence</td>
<td>Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td>Insufficient Evidence</td>
<td>None related to youth</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
</tbody>
</table>

* Generic available
+ XR, extended-release
** While loperidone alone can cause QTc prolongation, concomitant administration with a CYP2D6 inhibitor (e.g., paroxetine) or a CYP3A4 inhibitor (e.g., ketoconazole) can double QTc prolongation compared with administering loperidone alone. No long-acting injectable antipsychotic formulations are FDA-approved for use in children and adolescents.
# Antipsychotics: First Generation (Typical)

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Patient Monitoring Parameters</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
</table>
| Chlorpromazine* | Thorazine®    | • Age > 6 months: 0.25 mg/lb every 4-6 hours, as needed  
• Adolescents: 10-25 mg/dose every 4-6 hours | • Age < 5 years: 40 mg/day  
• Age 5-12 years: 75 mg/day  
• Age > 12 years: 800 mg/day | Approved for treatment of severe behavioral problems (age 6 months-12 years)  
• Outpatient Children: 0.55 mg/kg every 4-6 hours, as needed  
• Inpatient Children: 500 mg/day | One to six times daily | Same as Second Generation Antipsychotics | None related to youth | • Tardive Dyskinesia  
• Neuroleptic Malignant Syndrome  
• Leukopenia, neutropenia, and agranulocytosis  
• Drowsiness  
• Orthostatic hypotension  
• EKG changes  
• Extrapyramidal symptoms  
• Ocular changes  
• Hyperprolactinemia  
• Anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention)  
• Risk of prolonged QTc interval and torsades de pointes (particularly with pimozide) |
| Haloperidol*    | Haldol®      | • Age 3-12 years weighing  
○ 15-40 kg: 0.025-0.05 mg/kg/day  
○ ≥ 40 kg: 1 mg/day  
• Age > 12: 1 mg/day | • Age 3-12 years: 0.15 mg/kg/day or 6 mg/day, whichever is less  
• Age >12 years  
○ Acute agitation: 10 mg/dose  
○ Psychosis: 15 mg/day  
○ Tourette’s Disorder: 15 mg/day | Approved for treatment of Psychotic Disorders, Tourette’s Disorder, and severe behavioral problems (age ≥3 years):  
• Psychosis: 0.15 mg/kg/day  
• Tourette’s Disorder and severe behavioral problems: 0.075 mg/kg/day  
• Severely disturbed children: 6 mg/day | One to three times daily | None related to youth | None related to youth | None | |
| Perphenazine*   | Trilafon®    | • Age 6-12 years: Insufficient Evidence  
• Age > 12 years: 4-16 mg two to four times daily | • Age 6-12 years: Insufficient Evidence  
• Age > 12 years: 64 mg/day | Approved for treatment of Psychotic Disorders (age ≥12 years):  
• Outpatient: 24 mg/day  
• Inpatient: 64 mg/day | Two to four times daily | None related to youth | None related to youth | None | |
| Pimozide        | Orap®        | Age ≥7 years: 0.05 mg/kg  
• Age 7-12 years: 6 mg/day or 0.2 mg/kg/day, whichever is less  
• Age ≥ 12 years: 10 mg/day or 0.2 mg/kg/day, whichever is less | | Approved for treatment of Tourette’s Disorder (age ≥12 years): 10 mg/day or 0.2 mg/kg/day, whichever is less | Once or twice daily | None | None | None |
### Mood Stabilizers

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)*</th>
<th>Initial Dosage</th>
<th>Target Dosage Range</th>
<th>Literature Based Maximum Dosage for Children and Adolescents</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Patient Monitoring Parameters</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine*</td>
<td>Ziaxin® (tab, oral suspension, chewable)</td>
<td>Age 4-5: 10-20 mg/kg/day</td>
<td>Age 6-12: 800-800 mg/day</td>
<td>Age 13-15: 1000 mg/day</td>
<td>Age &gt;15: 1200 mg/day</td>
<td>Two to four times daily</td>
<td>CBC with differential — baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated</td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Tegretol® (tab)</td>
<td>Age 4-6: 38 mg/kg/day</td>
<td>Age 6-12: 50 mg/kg/day</td>
<td>Age 13-15: 1000 mg/day</td>
<td>Age &gt;15: 1200 mg/day</td>
<td>Two to four times daily</td>
<td>CBC with differential — baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated</td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>(extended release capsule)</td>
<td>/ day or 200 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Electrolytes — baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated</td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Equetro® (extended release capsule)</td>
<td>Age ≥ 13 years: 450 mg/ day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pregnancy Test — baseline and 3-4 weeks after dose adjustment, then as clinically indicated</td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Depakote® delayed-release tablets</td>
<td>Age ≥ 6 years: 125 µg/mL/day</td>
<td>Age ≥ 10 years: 60 mg/kg/day</td>
<td>Approved for treatment of Seizure Disorders (age ≥ 10 years)</td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Depakote® ER extended-release tablets</td>
<td>Age ≥ 10 years: 50-100 µg/mL, or 60 mg/kg/day</td>
<td></td>
<td>Maximum dose based upon serum level: 50-100 µg/mL, or 60 mg/kg/day</td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Depakote® sprinkles</td>
<td>Age ≥ 5 years: 60 mg/kg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Divalproex Sodium*</td>
<td>Age ≥5 years: 10-15 mg/kg/day</td>
<td>Age ≥6 years: Serum level: 125 µg/mL/day</td>
<td>Approved for treatment of Seizure Disorders (age ≥ 10 years)</td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Eskalti®</td>
<td>Age ≥ 6.11 years: Lesser of 15-20 mg/kg/day or 150mg twice per day</td>
<td>Dose adjustment based upon serum level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Eskalti®CR</td>
<td>Age ≥ 6.12 years: Lesser of 15-20 mg/kg/day or 300 mg twice per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Lithobid®(ER)</td>
<td></td>
<td>Age ≥6 years: Serum level: 1.2 mEq/L or 1800 mg</td>
<td>Approved for treatment of manic episodes and maintenance of Bipolar Disorder (age ≥ 12 years)</td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td></td>
<td>Lithium*</td>
<td></td>
<td>12 hour post dose serum level: 0.6-1.2 mEq/L</td>
<td>Maximum dose based upon 12 hour post dose serum level: 1.2 mEq/L</td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
</tbody>
</table>

*Generic Available
ER and XR, extended-release; CR, controlled release

(Continued on Page 16)

March 2016
(Tables Updated July 2016)
## Mood Stabilizers (continued)

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dosage</th>
<th>Target Dosage Range</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Patient Monitoring Parameters</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamotrigine*</td>
<td>Lamictal®</td>
<td>• Age 6-11 years: 25 mg/day</td>
<td>Age 6-11 years: • Monotherapy: Age 2-12: 400 mg/day Age &gt;12: 500 mg/day • With Valproate: use &gt; 200 mg/day in adults for bipolar depression has not conferred additional efficacy</td>
<td>Approved for adjunctive therapy for Seizure Disorders: • Renal Function - baseline and as clinically indicated</td>
<td>Once or twice daily</td>
<td>Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established</td>
<td>Serious rashes including Stevens-Johnson syndrome</td>
<td>• Dermatological reactions</td>
<td></td>
</tr>
<tr>
<td>Oxcarbazepine*</td>
<td>Trileptal®</td>
<td>8-10 mg/kg/day</td>
<td>Monotherapy (based on weight): Age 7-12 years: 60 mg/kg/day or 1500 mg/day Age 13-17 years: 60 mg/kg/day or 2100 mg/day Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established</td>
<td>Approved for treatment of Seizure Disorders as mono-therapy (age ≥4 years), or as adjunctive therapy in (age ≥2 years): 60 mg/kg/day or 1800 mg/day</td>
<td>Twice daily</td>
<td>Safety and effectiveness for treatment of Seizure Disorders: • Electrolytes – baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated</td>
<td>None</td>
<td>• Hyponatremia (incidence may be as high as 24% in children)</td>
<td></td>
</tr>
</tbody>
</table>

* Generic Available
+ ER and XR, extended-release; CR, controlled release
+ EIAED’s - Enzyme Inducing Anti-Epileptic Drugs (e.g. Carbamazepine, Phenobarbital, Phenytoin, Primidone)
<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage**</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Black Box Warning**</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
</table>
| Diphenhydramine* | Benadryl® | • Age 3-5 years: 6.25-12.5 mg (1mg/kg max)  
• Age 5-11 years: 12.5-25 mg  
• Age ≥12 years: 25-50 mg | • 25-37 lbs: 12.5 mg  
• 38-49 lbs: 19 mg  
• 50-99 lbs: 25 mg  
• ≥100 lbs: 50 mg  
Evidence suggests that tolerance develops to the hypnotic effects of diphenhydramine within 5-7 nights of continuous use. | Approved for treatment of insomnia (age ≥12 years): 50 mg at bedtime | Once at bedtime | None |
| Trazodone* | Desyrel® | • Children: Insufficient Evidence  
• Adolescents: 25 mg | • Children Insufficient Evidence  
• Adolescents: 100 mg/day | Not approved for children or adolescents as a hypnotic | Once at bedtime | Increased the risk compared to placebo of suicidal thinking and behavior (Suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders |
| Eszopiclone | Lunesta® | Insufficient Evidence | Insufficient Evidence | Not approved for children or adolescents | Once at bedtime | None |
| Melatonin | No brand name | • Age 3-5 years: 0.5mg  
• Age ≥6 years: 1mg | • Age 3-5 years: 0.15 mg/kg or 3 mg, whichever is less  
• Age ≥6 years: 0.15mg/kg or 6mg, whichever is less | Regulated by FDA as a dietary supplement and not as a medication (no FDA approved indications) | Once at bedtime or alternatively, give 5-6 hrs before Dim Light Melatonin Onset (DLMO) | None |
| Ramelteon | Rozerem® | Insufficient Evidence | Insufficient Evidence | Not approved for children or adolescents | Insufficient Evidence | None |
| Hydroxyzine* | Vistaril® | • Age 3-5 years: 25 mg  
• Age ≥6 years: 50mg | • Age 3-5 years: 25 mg  
• Age 6-11 years: 50mg  
• Age 12 years and older: 100 mg | Approved for treatment of anxiety and tension:  
• Age <6 years: 50 mg/day in divided doses  
• Age ≥6 years: 50-100 mg/day in divided doses  
Approved as a sedative when used as a premedication and following general anesthesia: 0.6 mg/kg | Once at bedtime | None |

* Generic Available

** Maximum doses for the sedative/hypnotics are based upon night time doses to induce sleep in a child with severe insomnia.
Glossary

ANC = ABSOLUTE NEUTROPHIL COUNT

BMI = Body Mass Index. A measure of body fat based upon height and weight.

CBC = Complete blood count. Lab test used to monitor for abnormalities in blood cells, e.g., for anemia.

Cp = Plasma concentration

Serum creatinine = A lab test used to calculate an estimate of kidney function.

EKG = Electrocardiogram

EEG = Electroencephalogram

EPS = Extrapyramidal side effects. These are adverse effects upon movement, including stiffness, tremor, and severe muscle spasm

FDA = U.S. Food and Drug Administration

Hemoglobin A1c = A laboratory measurement of the amount of glucose in the hemoglobin of the red blood cells. Provides a measure of average glucose over the previous 3 months.

LFTs = Liver function tests

MAOIs = Monoamine Oxidase Inhibitors

MRI = Magnetic resonance imaging

PRN = as needed

Prolactin = A hormone produced by the pituitary gland

TFTs = Thyroid Function Tests
References


Biederman et al. A prospective open-label trial of lamotrigine monotherapy in children and adolescents with bipolar disorder. CNS Neurosci Ther Apr 2010;16(2):91-102


References (continued)


References (continued)


References (continued)


Web Link References


When to seek referral or consultation with a child or adolescent psychiatrist. American Academy of Child and Adolescent Psychiatry, 2003. http://www.aacap.org/AACAP/Member_Resources/Practice_Information/When_to SEEK_Re Referral_or_Consultation_with_a_CAP.aspx
Members of the Ad Hoc Working Group on Psychotropic Medication Parameters for Children and Youth in Foster Care

Chairs:
M. Lynn Crismon, PharmD: Psychopharmacologist, Dean, James T. Doluisio Regents Chair & Behrens Centennial Professor, College of Pharmacy, The University of Texas at Austin, Austin, TX.
James A. Rogers, MD: Child Psychiatrist, Medical Director, Texas Department of Family and Protective Services, Austin, TX.
Emilie Becker, MD: Child Psychiatrist, Medicaid/CHIP Mental Health Medical Director, Texas Health and Human Services Commission, Austin, TX.

Members:
Joseph Blader, PhD: Clinical Psychologist, Meadows Foundation & Semp Russ Professor of Child Psychiatry Research, Departments of Psychiatry and Pediatrics, The University of Texas Health Science Center at San Antonio, San Antonio, TX.
Angela Hughes Campbell, PharmD: Psychopharmacologist, Adjunct Assistant Professor, College of Pharmacy, The University of Texas at Austin, Nacogdoches, TX.
Mark Janes, MD: Child Psychiatrist, Medical Director, Bluebonnet Trails Community Services, Round Rock, TX.
Christopher J. Kratochvil, MD: Child Psychiatrist, Associate Vice Chancellor for Clinical Research, Chief Medical Officer UNeHealth, University of Nebraska Medical Center, Omaha, NE.
Molly Lopez, PhD: Clinical Psychologist, Research Associate Professor, School of Social Work, The University of Texas at Austin, Austin, TX.
James Lukefahr, MD: Pediatrician, Medical Director-Center for Miracles, Professor, Division of Child Abuse Pediatrics-The University of Texas Health Science Center, San Antonio, TX.
Octavio N. Martinez, Jr., MD: Psychiatrist, Executive Director-Hogg Foundation for Mental Health, The University of Texas at Austin, Austin, TX.
Nina Jo Muse, MD: Child Psychiatrist, Medical Director for Behavioral Health, Texas Department of State Health Services, Austin, TX.
Sylvia Muzquiz-Drummond, MD: Child Psychiatrist, Medical Director MHMRA of Harris County, Houston, TX.
Steven Pliszka, MD: Child Psychiatrist, Dielmann Distinguished Professor and Chair, Department of Psychiatry, The University of Texas Health Science Center, San Antonio, TX.
Dawnelle Schatte, MD: Child Psychiatrist, Dielmann Distinguished Professor and Chair, Department of Psychiatry, The University of Texas Health Science Center, San Antonio, TX.
Manuel Schydlower, MD: Pediatrician, Professor of Pediatrics, Associate Dean for Admissions, Texas Tech University Health Sciences Center, Paul L. Foster School of Medicine, El Paso, TX.

Observer/Monitors:
Amanda Garner, PharmD, Director of DUR/Formulary Management, Medicaid/CHIP Vendor Drug Program, Texas Health & Human Services Commission, Austin, TX.
Kay Lester, RPh, Pharmacy Benefit Oversight, Medicaid/CHIP Vendor Drug Program, Texas Health & Human Services Commission, Austin, TX.

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Dr. Blader has received funding as a consultant/researcher from Supernus Pharmaceuticals and research funding through his employer institution from Supernus.
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Dr. Lopez holds stock in Lilly, Merck, Proctor & Gamble, and Pfizer Pharmaceuticals.
Dr. Pliszka has received funding as a consultant for Ironshore and Shire Pharmaceuticals. Through his employer institution he has served as an expert witness for Eli Lilly and Jansen Pharmaceuticals. He has received research grants through his employer institution from Ironshore, Purdue and Shire.
The other members of the working group do not have any financial relationships to disclose.
Disclaimer

The authors of this document have worked to ensure that all information in the parameters is accurate at the time of publication and consistent with general psychiatric and medical standards and consistent with FDA labeling and information in the biomedical literature.

However, as medical research and practice continue to advance, therapeutic standards may change, and the clinician is encouraged to keep up with the current literature in psychiatry and clinical psychopharmacology. In addition, not all potential adverse drug reactions or complications are listed in the tables, and the clinician should consult the official FDA labeling and other authoritative reference sources for complete information.

These parameters are not a substitute for clinical judgement, and specific situations may require a specific therapeutic intervention not included in these parameters.

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Web Address for the March 2016 Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care

http://www.dfps.state.tx.us/Child_Protection/Medical_Services/guide-psychotropic.asp