Psychotropic Medication Guidelines for Youth in Care with the Indiana Department of Child Services

Approved 2/22/2018

Developed by the Indiana Psychotropic Medication Advisory Committee (PMAC), Psychotropic Advisory Subcommittee

2018 Psychotropic Advisory Subcommittee Members:
Leslie Hulvershorn, MD, Chair
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About the Indiana Psychotropic Medication Advisory Committee (PMAC)

The Indiana Psychotropic Medication Advisory Committee (PMAC) was launched in January, 2013 to review the psychiatric treatment of DCS-involved youth, with a specific focus on psychotropic medication utilization patterns. This committee includes representatives from IUSM Department of Psychiatry, DCS, OMPP, DMHA, pediatricians, social workers, psychologists, pharmacists, child advocates and other identified stakeholders (see 2014 members below; see current, 2018 members below). The PMAC monitors Federal legislation, reviews best-practice guidelines for psychotropic medication use, monitors Indiana prescription patterns, reviews formularies and makes policy recommendations to DCS. Specific responsibilities of the committee include the following:

- Review the literature on psychotropic medication best practice (e.g., AACAP) and provide guidance to DCS, OMPP, IUSM and prescribing providers;
- Provide assistance to DCS in establishing a consultation program for youth in state care who are prescribed psychotropic medications;
- Publish guidelines for the utilization of psychotropic medications among DCS-involved youth, with revisions made on a semi-annual basis, as needed;
- Review DCS policies for requesting and obtaining consent to treat DCS-involved youth with psychotropic medications and make recommendations for change to DCS Permanency and Practice Support Division; and
- Identify non-pharmacologic, evidence-based mental health treatments for DCS-involved youth.

Founding (2014) PMAC Members:

Elayne Ansara, PharmD, Pharmacist, Roudebush VAMC
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Char Burkett-Simms, Regional Manager, Indiana Department of Child Services
Melissa Butler, PhD, Clinical Psychologist, LaRue Carter State Hospital
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I. Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care, 5th Version, March/July 2016 (for Texas Department of Family and Protective Services)

Introduction:
In an attempt to provide improved utilization of psychotropic medications and therefore overall mental health care to Indiana’s children in the placement and care of the Department of Child Services (DCS), DCS convened a work group in 2013 to lead this effort. To guide Indiana’s prescribers, this work group, the Indiana Psychotropic Medication Advisory Committee (PMAC) agreed to adopt the September 2013 version of the Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care (“Texas parameters;” TP) developed by the Texas Department of Family and Protective Services and The University of Texas at Austin College of Pharmacy (for current version, see Appendix I). To consider the applicability of the Texas parameters, the PMAC tasked its Psychotropic Advisory Subcommittee with a review of the Texas parameters. As a result of this review, the Subcommittee recommended adoption of the Texas parameters with the following modifications/clarifications and additions.

In February, 2015, upon the recommendation of the Indiana Medicaid Mental Health Quality Advisory Committee (MHQAC), the Indiana Medicaid Drug Utilization Review (DUR) Board approved exempting drug therapy regimens, based upon recommendations from the IUSM Department of Psychiatry, from prior authorization (PA). Subsequently, managed care entities (MCEs) administering pharmacy benefits for affected youth agreed to participate in this program and adopted the PA exemption process.

A revision was completed January 2016. This current version was revised, incorporating updated Texas parameters (Version 5), January 2018.

I. Modifications/Clarifications:

General Principles:

1. In the state of Indiana, a comprehensive evaluation prior to the use of medications should be performed by a licensed professional or a qualified professional under the supervision of a licensed professional.

2. To clarify, a physical examination is not typically completed by a child psychiatrist or necessarily required for the use/start of psychotropic medications (excluding evaluation for extrapyramidal or other movement side effects). If warranted, it is the responsibility of the evaluating mental health professional to refer the child for a physical examination.

3. A standardized trauma assessment (e.g., CANS, Trauma Symptom Checklist) is preferred for clinical assessment of exposure of trauma and maltreatment. For youth with more extensive trauma histories, a comprehensive trauma assessment may recommended by DCS. The service standard for comprehensive trauma assessments can be found at http://www.in.gov/dcs/3159.htm.
4. In addition to the need to identify DSM-5 diagnoses to direct treatment, diagnoses outlined in the relevant version of the International Classification of Diagnoses (e.g., ICD-10) are also appropriate.

5. In addition to diagnoses, benefits/risk, lab findings, adverse events, alternatives, and risks of no treatment, informed consent should also include a discussion of possible medication interactions.

6. If a child does not improve in the care of a non-child psychiatrist, TP recommends referral to a child psychiatrist. We would like to clarify that the window for expected improvement for most childhood psychiatric disorders is 3 months.

7. When treating youth with medication for aggression, TP recommend a slow taper with discontinuation every 6 months. To clarify, youth with aggression resulting from any of the following disorders should be given an opportunity for a taper: oppositional defiant disorder, conduct disorder, disruptive mood dysregulation disorder, developmental disabilities and autism spectrum disorder. We would like to further note that such tapers may not be routine in current clinical practice, but they are now highly recommended.

Medication-Specific Recommendations

1. Although short acting alpha agonists for use in the treatment of ADHD and tics are not FDA approved, they remain the recommended first line agents.

2. Tapering antipsychotics in children may require longer than a 4 week period.

3. See Tables for additions

4. Routine lipid screening is recommended annually, rather than every 6 months, as outlined in the TP. If abnormal values are detected, more frequent monitoring (every 3-6 months) is recommended.

5. Fasting lipids and glucose are recommended to be checked on every pediatric patient prior to starting (or at first contact if medication has already been started) medications known to impact these labs (e.g., antipsychotics).

6. Evaluation of blood pressure, heart rate, weight and height is recommended for every medication monitoring visit and initial evaluation.

7. Clomipramine is recommended for obsessive compulsive disorder if the child or adolescent has failed two complete trials of serotonin reuptake inhibitors.

8. Due to concerns about the potential for cardiac conduction abnormalities, citalopram should not be prescribed at doses greater than 40 mg daily.

9. Orap (pimozide) should be used for the treatment of tics only if Haldol use was a failure or intolerable.

10. Aripiprazole dosage for the treatment of tics is as follows (per package instructions):

<table>
<thead>
<tr>
<th>Patient Weight</th>
<th>Start dose</th>
<th>Recommended dose</th>
<th>Maximum dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 kg</td>
<td>2 mg</td>
<td>5 mg</td>
<td>10 mg</td>
</tr>
<tr>
<td>&gt;/= 50 kg</td>
<td>2 mg</td>
<td>10 mg</td>
<td>20 mg</td>
</tr>
</tbody>
</table>

II. Additions:
General:

1. Rating scales used to identify response to treatment can be identified in numerous sources. A large number of evidence-based assessment tools are available free of charge for provider use in the DSM-5 (www.psychiatry.org/practice/dsm/dsm5/online-assessment-measures).

2. We would like to call special attention to best practices for care of very young children, particularly those laid out in Gleason et al, 2007 (see Appendix II).

3. Given problematic weight gain among youth on psychotropic agents, diet and exercise counseling with referrals to primary care physicians, dieticians and specialized pediatricians is recommended for any child with weight changes, ideally early in the treatment course.

4. Conversely, youth on stimulants who are unable to gain weight at a rate appropriate for age should be assessed for stimulant dosage reduction or discontinuation. Dietary counseling is recommended.

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 differ from those set out in the TP and are intended to fully replace page 8 of the 2013 TP. 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 complete DSM-5 (or comparable ICD-10) diagnosis in the youth’s medical record
2. Four (4) or more psychotropic medications prescribed concomitantly
3. Any psychotropic medication prescribed to a child less than one (1) year of age
4. Prescribing of:
   - Stimulants to a child less than three (3) years of age
   - Antipsychotics to a child less than four (4) years of age
   - Antidepressants to a child less than four (4) years of age
   - Mood stabilizers to a child less than four (4) years of age
5. The psychotropic medication dose exceeds usual recommended doses (FDA and/or literature based maximum dosages).
6. The prescribed psychotropic medication is not consistent with the appropriate care for the patient’s diagnosed mental disorder or with documented target symptoms usually associated with a therapeutic response to the medication prescribed.
7. Psychotropic polypharmacy (2 or more medications) for a given mental disorder is prescribed before utilizing psychotropic monotherapy.
8. Prescribing of:
   - Two (2) or more concomitant stimulants
- Two (2) or more alpha-2 agonists, including the combination of short- and long-acting agents (i.e. clonidine ER plus clonidine immediate release)
- Two (2) or more concomitant antidepressants
- Two (2) or more lithium-based agents
- Three (3) or more concomitant lithium-based mood stabilizers or other mood stabilizers (e.g., anticonvulsants)
- Two (2) or more antipsychotics
- Three (3) or more sedative-hypnotics
- Two (2) or more benzodiazepines
- Any long acting injectable antipsychotic
- Excessive (2 weeks of 4 or more days with PRN use) or inappropriate (3 or more at once; high dose) PRN medication use

*The prescription of a long-acting stimulant and an immediate release stimulant of the same chemical entity (e.g., methylphenidate) does not constitute concomitant prescribing.

9. Use medications (in a particular age range, when specified) when no evidence exists to support their use for psychiatric indications:

**Stimulants and alternatives**
amphetamine aspartate/amphetamine sulfate/dextroamphetamine (< 3 yrs)
nortriptyline

**Antidepressants**
isocarboxazid (< 16 yrs)
phenelzine sulfate (< 13 yrs)
tranylcypromine sulfate (< 13 yrs)

**Antidepressants, SSRIs**
paroxetine HCl/mesylate

**Antidepressants, TCAs**
amitriptyline HCl (< 13 yrs)
amoxapine (< 16 yrs)
nortriptyline (< 13 yrs)

**Antipsychotics, Typical**
thioridazine HCl (< 2 yrs)

**Barbiturates**
Butisol

**Benzodiazepines**
chlordiazepoxide HCl (< 6 yrs)
Mood Stabilizers
divalproex sodium (< 10 yrs)
valproic acid (< 2 yrs)
valproate sodium (< 2 yrs)
lamotrigine (< 2 yrs)

III. Tables:
To address new medications or additional information, the following tables have been added, in order to supplement the tables provided in the TPs. [Abbreviations used in tables: Insufficient evidence=IE; Food and Drug Administration=FDA; NA= Not FDA approved for children or adolescents (i.e., safety and effectiveness in pediatric patients has not been established); milligram = mg]

Table 1. Long-Acting Injectable Psychotropic Medications

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol decanoate</td>
<td>Haldol® decanoate</td>
<td>50mg</td>
<td>100mg</td>
<td>NA</td>
<td>Monthly</td>
</tr>
<tr>
<td>Fluphenazine decanoate</td>
<td></td>
<td>--</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Risperidone long-acting injection</td>
<td>Risperdal® Consta®</td>
<td>--</td>
<td>25mg</td>
<td>NA</td>
<td>Every 2 weeks</td>
</tr>
<tr>
<td>Paliperidone palmitate</td>
<td>Invega®</td>
<td>--</td>
<td>39mg/273mg, 410mg, 546mg, 819mg</td>
<td>NA</td>
<td>Monthly for Sustenna Every 3 months for Trinza</td>
</tr>
<tr>
<td>Olanzapine for extended release injectable suspension</td>
<td>Zyprexa® Relprevv™</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Aripiprazole for extended release injectable suspension</td>
<td>Abilify Maintena™</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Aripiprazole lauroxil extended-release injectable suspension</td>
<td>Aristada™</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Naltrexone for extended</td>
<td>Vivitrol®</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
</tbody>
</table>
References:

Warnings and precautions, including black box warnings are the same as the oral preparations except for a delirium/sedation syndrome (including agitation, anxiety, confusion, disorientation) that has been observed following use of Zyprexa Relprevv.

### Table 2. Sedative-Hypnotics Agents

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dosage</th>
<th>Literature Based Max Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Black Box</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zolpidem</td>
<td>Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist</td>
<td>≤ 17 years: 0.25mg/kg at bedtime¹</td>
<td>0.5mg/kg OR 20mg¹</td>
<td>NA</td>
<td>Nightly</td>
<td>--</td>
</tr>
<tr>
<td>Zaleplon</td>
<td>Sonata</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

**Warnings and Precautions:**

**Adverse Psychiatric Events:** Abnormal thinking and behavioral changes (e.g., aggressiveness, uncharacteristic extroversion, bizarre behavior, agitation, hallucinations, depersonalization, amnesia) may occur unpredictably. Possible worsening of depression (including suicidal thinking) with sedative or hypnotic use in patients with depression. Immediately evaluate any new behavioral sign or symptom.

**Complex Sleep-related Behaviors:** Complex behaviors such as sleep-driving (i.e., driving while not fully awake after ingesting a sedative and hypnotic drug, with no memory of the event), preparing and eating food, making phone calls, or having sex while not fully awake after taking a sedative and hypnotic drug, and usually with no memory of the event, reported.

**Withdrawal Effects:** Rapid dosage reduction or abrupt discontinuance of sedatives or hypnotics has resulted in signs and symptoms of withdrawal.

**Abuse Potential:** Abuse potential similar to that of benzodiazepines and related hypnotics.
Sensitivity Reactions: Angioedema involving the tongue, glottis, or larynx reported rarely following initial or subsequent doses of sedative and hypnotic drugs, including zolpidem. Some patients experienced additional symptoms (e.g., dyspnea, closing of the throat, nausea and vomiting [suggestive of anaphylaxis]). Some individuals required medical treatment in an emergency department. Angioedema reported during post-marketing surveillance.

References:

Table 3. Other Antipsychotics.

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Trade name</th>
<th>Initial dosage</th>
<th>Maximum dosage</th>
<th>FDA max</th>
<th>Schedule</th>
<th>Black Box</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cariprazine</td>
<td>Vraylar</td>
<td>IE</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>Mortality in Elderly Patients with dementia</td>
<td>same</td>
</tr>
<tr>
<td>Thioridazine</td>
<td>Mellaril</td>
<td>0.5 mg/kg/d</td>
<td>3mg/kg/d</td>
<td>800 mg</td>
<td>TID</td>
<td>QT changes Mortality in Elderly Patients with dementia Tardive Dyskinesia NMS Leukopenia</td>
<td></td>
</tr>
<tr>
<td>Trifluperazine</td>
<td>Stelazine</td>
<td>1 mg</td>
<td>15 mg</td>
<td>Q-BID</td>
<td>same</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Loxapine</td>
<td>Loxitane</td>
<td>10 mg</td>
<td>250 mg/d</td>
<td>same</td>
<td>same</td>
<td>same</td>
<td>same</td>
</tr>
</tbody>
</table>

Notes:
- Trifluperazine is labeled for “Children, ages 6 to 12, who are hospitalized or under close supervision.”
- Loxapine—Very limited data on use in children; Label has no information on children. An OVID search of “loxapine & children” found only one positive case report 5 mg tid is positive in a child who had dystonia on Haldol, elevated AST on risperidone & olanzapine, no effect of quietapine by history( J Child Adolesc Psychopharm V16 2006, pp 639-634) and one letter to the editor about an 8 year old boy who overdosed on 15 ml when prescribed 0.6 ml. Dose listed above is from table on p 233 of Wolraich et al. Developmental-Behavioral Pediatrics: Evidence and Practice, 2008.
- Clinical Pharmacology: “Thioridazine has not been evaluated for use in children under the age of 2 years. Thioridazine should not be used to treat conditions in children for which specific pediatric dosages have not been established. There is no known indication for use of thioridazine in infants or neonates.”
- Older antipsychotics are no longer used commonly in children. Extrapyramidal movement disorders, QT changes and the increasing evidence base for newer “atypical antipsychotics” have much diminished their use. None are labeled for use in children. Newer textbooks frequently do not list them in in tables of treatment of children with disabilities. FDA labeling is often old without consideration of more recent standards.

Table 4. Tricyclic Antidepressants
<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dose</th>
<th>Lit. based max. dosage</th>
<th>FDA-Approved Max Dosage for Children and Adoles.</th>
<th>Schedule</th>
<th>Patient Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline (for depression)</td>
<td>Elavil</td>
<td>10 mg TID</td>
<td>IE</td>
<td>150mg daily (for 12 and above; not recommended in &lt;12)</td>
<td>Three times daily</td>
<td>Pulse ECG</td>
<td>Suicidality</td>
<td>• Use in combination with MAOIs • Suicidal ideation • Activation of mania/hypomania • Lowers seizure threshold • Discontinuation syndrome • Caution with cardiac disease</td>
</tr>
<tr>
<td>Clomipramine (for OCD) 10 and older</td>
<td>Anafranil</td>
<td>25 mg daily</td>
<td>IE</td>
<td>3 mg/kg/day or 200 mg, whichever is smaller</td>
<td>May give as single qHS dose once tolerated</td>
<td>Pulse ECG</td>
<td>See amitriptyline</td>
<td>See amitriptyline</td>
</tr>
<tr>
<td>Protriptyline (for depression)</td>
<td>Vivactil</td>
<td>5 mg TID</td>
<td>IE</td>
<td>60 mg daily (for 12 and above?)</td>
<td>Three to four times daily</td>
<td>Pulse ECG</td>
<td>See amitriptyline</td>
<td>See amitriptyline</td>
</tr>
<tr>
<td>Imipramine (in children, efficacy established for nocturnal enuresis only)</td>
<td>Tofranil</td>
<td>30 mg daily for teens</td>
<td>IE</td>
<td>2.5 mg/kg/day in children; doses above 100 mg daily in teens “generally not necessary”</td>
<td>Divided doses</td>
<td>Pulse ECG</td>
<td>See amitriptyline</td>
<td>See amitriptyline • Methylphenidate raises blood level • Imipramine may block clonidine effect</td>
</tr>
<tr>
<td>Desipramine</td>
<td>Norpramine</td>
<td>25 mg IE</td>
<td>Usual maximum 100 mg daily; up to 150 mg in more severely ill</td>
<td>Daily dose</td>
<td>Pulse ECG</td>
<td>See amitriptyline and imipramine</td>
<td>See amitriptyline and imipramine</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Medications used to treat substance use disorders

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dose</th>
<th>Lit. based max. dosage</th>
<th>FDA-Approved Max Dosage for Children and Adoles.</th>
<th>Schedule</th>
<th>Patient Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naltrexone (IM) Or orally dosed naltrexone (PO; revia)</td>
<td>Vivitrol (IM)</td>
<td>380 mg (IM) or 25 mg (PO)</td>
<td>IE</td>
<td>None (FDA approved in adults for treatment of alcohol and opioid use disorders)</td>
<td>Once monthly (IM) and once-twice daily (PO)</td>
<td>Urine drug screen (must be abstinent for 7 days) Liver functions</td>
<td>None</td>
<td>• Can precipitate severe opioid withdrawal • Dose related hepatotoxicity</td>
</tr>
</tbody>
</table>
While no medication is FDA approved to treat substance use disorders in adolescents younger than 16, there is a pressing clinical need to judiciously use such medications, at times. A small number of case reports and clinical trials suggest that each of these medications can be efficacious when used appropriately in adolescents, while no research supports their use in children.

### Table 6. New Stimulant Preparations

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dose</th>
<th>Lit. based max. dosage *</th>
<th>FDA-Approved Max Dosage for Children and Adoleses.</th>
<th>Schedule</th>
<th>Patient Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings/Precautions &amp; Additional Info</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextroamphetamine sulfate</td>
<td>Zenzedi</td>
<td>Age 3-5: 2.5mg/day, Age ≥6: 5mg once or twice daily</td>
<td>Age 3-5: 40mg/day, Age ≥6: 40mg/day</td>
<td>Once or twice daily; 2nd dose should be administered at 4-6 hours interval</td>
<td>Same as other dextroamphetamine products</td>
<td>High potential for abuse and dependence</td>
<td>Immediate release tablets</td>
<td></td>
</tr>
</tbody>
</table>

*As these are simply new preparations of long established medications, the literature based maximum dose is specific for the product itself, and not the compound.

### Table 7. Literature-based ADHD Medication Dosage by Weight
<table>
<thead>
<tr>
<th>Medication</th>
<th>Mg/kg/day</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stimulants</strong></td>
<td></td>
</tr>
<tr>
<td>Dexmethylphenidate</td>
<td>0.5-1.0</td>
</tr>
<tr>
<td>Dextroamphetamine</td>
<td>0.3-1.0</td>
</tr>
<tr>
<td>Mixed amphetamine salts</td>
<td>0.5-1.5</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>1.0-2.0</td>
</tr>
<tr>
<td><strong>Non-stimulants</strong></td>
<td></td>
</tr>
<tr>
<td>Atomoxetine</td>
<td>0.5-1.4</td>
</tr>
<tr>
<td>Clonidine</td>
<td>0.003-0.010</td>
</tr>
<tr>
<td>Guanfacine</td>
<td>0.015-0.05</td>
</tr>
</tbody>
</table>

Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care (5th Version)

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

March 2016
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Psychotropic Medication Utilization Parameters

March 2016
(Tables Updated July 2016)

Introduction and General Principles

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 the case of an emergency, a child should receive a thorough health history, psychosocial assessment, mental status exam, and physical exam before prescribing a psychotropic medication. The physical assessment should be performed by a physician or another healthcare professional qualified to perform such an assessment. It is recognized that in some emergency situations, it may be in the best interest of the child to prescribe psychotropic medications before a physical exam can actually be performed. In these situations, a thorough health history should be performed to assess for significant medical disorders and past response to medications, and a physical evaluation should be performed as soon as possible. A thorough psychosocial assessment should be performed by an appropriately qualified mental health clinician (masters or doctoral level), a psychiatrist/child psychiatrist, or a primary care physician with experience in providing mental health care to children and youth. The child's symptoms and functioning should be assessed across multiple domains, and the assessment should be developmentally age appropriate. It is very important that information about the child's history, including history of trauma and current functioning be made available to the treating physician in a timely manner, either through an adult who is well-informed about the child or through a comprehensive medical record.

It is critical to meet the individual needs of patients and their families in a culturally competent manner. This indicates a need to address communication issues as well as differences in perspective on issues such as behavior and mental functioning. Interpretation of clinical symptoms and decisions concerning treatment should, whenever possible, be informed by the child's developmental history of trauma, neglect or abuse and the timing of these stressors. In general, optimal outcomes are achieved with well-coordinated team based care with members of different professions (e.g., child psychiatrist, child psychologist, social worker, primary care physician, etc.) each contributing their particular expertise to the treatment plan and follow-up. Additionally, at present there are no biomarkers to assist with the diagnosis of mental disorders, and imaging (e.g., MRI) and other tests (e.g., EEG) are not generally helpful in making a clinical diagnosis of a mental disorder.

The role of non-pharmacological interventions should be considered before beginning a psychotropic medication, except in urgent situations such as suicidal ideation, 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,
Psychotropic Medication Utilization Parameters

Monotherapy regimens for a given diagnosis are preferred, whenever possible, trauma-informed, evidence-based, and 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 medications prescribed.

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” (Southam-makosane 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

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

• A DSM-5 psychiatric diagnosis should be made before the prescrib ing 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 ongoing 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, appropriateness 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

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></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evekeo®</td>
<td>Age ≥ 6 years: 5-10 mg/day</td>
<td>Age ≥ 6 years: &gt;50 kg: 60 mg/day</td>
<td>Approved for children 6 years and older: 30 mg/day</td>
<td>Once daily</td>
<td>Baseline and ongoing: height, weight, heart rate, and blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adderall®XR</td>
<td>Age 3-5 years: 5 mg/day</td>
<td>Age 6-12 years: 5-10 mg/day</td>
<td>Age ≥ 13 years: 10 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amphetamine base</td>
<td>Adderall®XR-ODT (oral disintegrating tablet)</td>
<td>Age ≥ 6 years: 6.3 mg/day (3.1 mg = 5 mg Adderall®XR)</td>
<td>Age 6-12 years: 12.5 mg/day</td>
<td>Age 13-17 years: 12.5 mg/day</td>
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<td></td>
<td></td>
</tr>
<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>
<td></td>
<td></td>
</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>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Zenzedi®</td>
<td>Age ≥ 6 years: 5 mg twice daily</td>
<td>Age ≥ 6 years: &gt;50 kg: 80 mg/day</td>
<td>Age ≥ 6 years: 40 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Procentra®</td>
<td>Age 3-5 years: 5 mg/day</td>
<td>Age 3-5 years: 30 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dexedrine Spansule®</td>
<td>Age ≥ 6 years: 5 mg/day</td>
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</tr>
<tr>
<td>Lisdexamfetamine</td>
<td>Vyvanse®</td>
<td>Age 3-5 years: 10 mg/day</td>
<td>Age 3-5 years: 30 mg/day</td>
<td>Approved for children 6 years and older: 70 mg/day</td>
<td>Once daily</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.

+ XR, extended-release

(Continued on Page 9)

March 2016
(Tables Updated July 2016)
### 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>Ritalin®</td>
<td></td>
<td>Age ≥ 3 years: 10 mg/day</td>
<td>Age 3-5 years: 20 mg/day</td>
<td>Approved for children 6 years and older: 60 mg/day</td>
<td>One to three times daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylphenidate*</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: 20 mg/day</td>
<td>Twice daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ritalin®SR</td>
<td></td>
<td>Age ≥ 6 years: 5 mg twice daily</td>
<td>Age 6 years: 108 mg/day</td>
<td>Age 13-17 years: lesser of 72 mg/day or 2 mg/kg/day, whichever is less</td>
<td>Once daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daytrana®TD patch+</td>
<td>Daytrana®TD</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: 30 mg/day</td>
<td>Once daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amino®</td>
<td></td>
<td>Age ≥ 6 years: 10-20 mg/day</td>
<td>Age ≥ 6 years: 5-10 mg/day</td>
<td>Approved for children 6 years and older: 30 mg/day</td>
<td>Once daily</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
<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><strong>Atomoxetine</strong></td>
<td>Strattera®</td>
<td>• Age ≥ 6 years and weight ≤70 kg: 0.5 mg/kg/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</td>
<td>Suicidal ideation in children and adolescents being treated for ADHD</td>
<td>• Severe liver injury • Contraindicated to use within 14 days of an MAOI • Increased blood pressure and heart rate • Psychiatric adverse events • Priapism (rare)</td>
</tr>
<tr>
<td><strong>Catapres®</strong> (IR)</td>
<td>• Age ≥ 6 years and weight &lt;45 kg: 0.05 mg/kg/day</td>
<td>Age ≥ 6 years AND • Weight ≥ 27.5-40.5 kg: 0.2 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 • Personal and family cardiovascular history</td>
<td>None</td>
<td>• Hypotension • Bradycardia • Syncope • Sedation/Somnolence • Taper, do not discontinue abruptly CAUTION IF USED WITH ANTIPSYCHOTICS (↓ BP)</td>
<td></td>
</tr>
<tr>
<td><strong>Kapvay®</strong> (ER)</td>
<td>Age ≥ 6 years: 0.1 mg/day</td>
<td>Age ≥ 6 years: 0.4 mg/day</td>
<td>Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD (age 6-17 years): 0.4 mg/day</td>
<td>Once or twice daily</td>
<td>• Baseline and ongoing: heart rate and blood pressure • Personal and family cardiovascular history</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tenex®</strong> (IR)</td>
<td>• Age ≥ 6 years and weight &lt;45 kg: 0.5 mg/kg/day</td>
<td>Age ≥ 6 years AND • Weight ≥ 27.4-40.5 kg: 0.3 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>One to four times daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intuniv®</strong> (ER)</td>
<td>Age ≥ 6 years: 1 mg/day</td>
<td>Age ≥ 6-12 years: 4 mg/day</td>
<td>Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD • Age 6-12 years: 4 mg/day</td>
<td>Once</td>
<td>• Baseline and ongoing: heart rate and blood pressure • Personal and family cardiovascular history</td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Wellbutrin®</strong></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>• Blood pressure and Pulse • Mental status exam and suicide assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Buproprion®</strong></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></td>
<td></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></td>
</tr>
<tr>
<td><strong>Imipramine</strong></td>
<td>Tofranil®</td>
<td>Age ≥ 6 years: 1 mg/kg/day or 25 mg/day, whichever is less</td>
<td>Age ≥ 6 years: 4 mg/kg/day or 200 mg/day, whichever is less</td>
<td>Approved for treatment of enuresis in children • Age 6-11 years: 2.6 mg/kg/day or 50 mg/day, whichever is less • Age ≥ 12 years: 2.5 mg/kg/day or 75 mg/day, whichever is less</td>
<td>Twice daily</td>
<td>• CBC • Blood pressure and Pulse • EKG • Mental status exam and suicide assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nortriptyline®</strong></td>
<td>Aventyl®</td>
<td>Age ≥ 6 years: 0.5 mg/kg/day</td>
<td>Age ≥ 6 years: 2 mg/kg/day or 100 mg/day, whichever is less</td>
<td>Not approved for children and adolescents</td>
<td>Twice daily</td>
<td>• CBC • Blood pressure and Pulse • EKG • Mental status exam and suicide assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nortriptyline®</strong></td>
<td>Pamelor®</td>
<td>Same as above</td>
<td>450 mg/day</td>
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<td></td>
</tr>
</tbody>
</table>

* Generic available
+ IR, immediate release; SR, sustained-release formulation; ER, extended-release; XL, extended-length
## 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</td>
<td>• Age ≥ 6 years: 40 mg/day</td>
<td>Not approved for children and adolescents</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>• Age ≥ 12 years: 20 mg/day</td>
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<td></td>
</tr>
<tr>
<td>Escitalopram*</td>
<td>Lexapro®</td>
<td>• Age 6-11 years: 5 mg/day</td>
<td>• Age 6-11 years: 20 mg/day</td>
<td>• Not approved for children</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Age ≥ 12 years (MDD): 10 mg/day</td>
<td>• Age ≥ 12 years: 30 mg/day</td>
<td>• 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</td>
<td>• Age ≥ 6 years: 60 mg/day</td>
<td>• Approved for treatment of MDD (age 6-18 years): 20 mg/day; Approved for treatment of OCD (age 7-17 years): 60 mg/day</td>
<td>Once daily</td>
<td>• Pregnancy test – as clinically indicated</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></td>
<td></td>
<td>• Age ≥ 12 years: 10 mg/day</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Paroxetine*</td>
<td>Paxil®</td>
<td>• Children: Not recommended</td>
<td>• Children: Not recommended</td>
<td>Not approved for children and adolescents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Age ≥ 12 years: 10 mg</td>
<td>• Age ≥ 12 years: 40 mg</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Paxil®CR</td>
<td>• Children: Not recommended</td>
<td>• Children: Not recommended</td>
<td>Not approved for children and adolescents</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>• Age ≥ 12 years: 25 mg</td>
<td>• Age ≥ 12 years: 50 mg</td>
<td></td>
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</tr>
<tr>
<td>Fluvoxamine*</td>
<td>Luvox®</td>
<td>Age ≥ 8 years: 25 mg/day</td>
<td>• Age 8-11 years: 200 mg/day</td>
<td>Approved for treatment of OCD (age 8-17 years): 200 mg/day; Ages 12-17 years: 300 mg/day</td>
<td>Daily doses &gt;50 mg should be divided</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Age ≥ 8 years: 100 mg/day</td>
<td>• Age 12-17 years: 300 mg/day</td>
<td></td>
<td></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</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>
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<tr>
<td></td>
<td></td>
<td>• Age 13-17 years: 25-50 mg/day</td>
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</tr>
<tr>
<td>Vilazodone</td>
<td>Viibryd®</td>
<td>Insufficient Evidence</td>
<td>Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td></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.
### Antidepressants, SNRIs

<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>Venlafaxine*</td>
<td>Effexor®</td>
<td>Age 7-17 years: 37.5 mg/day</td>
<td>• Age 7-11 years: 150 mg/day or 375 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>IR: Two to three times 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 • Hypotension and syncope • Serotonin Syndrome • Seizures • Hypotension • Contraindicated for use within 14 days of an MAOI</td>
</tr>
<tr>
<td></td>
<td>Effexor®XR</td>
<td></td>
<td></td>
<td></td>
<td>XR: Once daily</td>
<td>• Monitor for emergence of suicidal ideation or behavior</td>
<td></td>
<td></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>• Blood pressure during dosage titration and as clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desvenlafaxine</td>
<td>Pristiq®</td>
<td>• Children: Insufficient Evidence</td>
<td>• Children: Insufficient Evidence</td>
<td>Not approved for children and adolescents</td>
<td>Once daily</td>
<td>• Monitor weight and growth</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Age 12-17 years: 50 mg/day</td>
<td>• Age 12-17 years: 100 mg/day</td>
<td></td>
<td></td>
<td>• Hepatic function testing – baseline and as clinically indicated</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>• CBC and EKG at baseline and as clinically indicated for Clomipramine</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>
<td>• Orthostatic hypotension and syncope</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Antidepressants, Other Mechanisms

<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>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</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 • Seizures • Hypotension • Contraindicated for use within 14 days of an MAOI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Monitor for emergence of suicidal ideation or behavior</td>
<td>In addition: Hepatotoxicity, Seizures, and Neutropenia Potential with Mirtazapine</td>
<td></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>• Blood pressure during dosage titration and as clinically indicated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Generic Available
+ XR, extended-release
<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 (oral solution) tab</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>Seroquel®</td>
<td>Seroquel (brand only)</td>
<td>Age 5-9 years: 12.5-25 mg/day</td>
<td>Approved for treatment of Bipolar Mania (age ≥ 10 years): 600 mg/day</td>
<td>Approved for treatment of Schizophrenia (13-17 years): 800 mg/day</td>
<td>IR: One to three times daily</td>
<td>• CBC as clinically indicated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Olanzapine*</td>
<td>Zyprexa®</td>
<td>Age 4-5 years: 1.25 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>• Pregnancy test – as clinically indicated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clozapine*</td>
<td>FazaClo® (oral disintegrating tablet)</td>
<td>Age 8-11 years: 6.25-12.5 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>Not approved for children and adolescents</td>
<td>Once or twice daily</td>
<td>• Blood pressure, pulse rate, height, weight and BMI measurement – at every visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lurasidone®</td>
<td>Latuda®</td>
<td>Age ≥ 10 years: 2.5 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>None related to youth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brexpiprazole</td>
<td>Rexulti®</td>
<td>Age ≥ 10 years: 2.5 mg twice daily</td>
<td>Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 5 mg/day</td>
<td>Approved for treatment of irritability associated with autistic disorder (age 5-16 years): 3 mg/day</td>
<td>None related to youth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ziprasidone*</td>
<td>Geodon®</td>
<td>Age 10-17 years: 20 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>Twice daily; take with ≥500 calorie meal</td>
<td>None related to youth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paliperidone*</td>
<td>Invega®</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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole*</td>
<td>Abilify®*</td>
<td>Age ≥ 4 years: 2 mg/day</td>
<td>Administration of a CYP2D6 inhibitor (e.g., paroxetine) or a CYP3A4 inhibitor (e.g., ketoconazole) can double QTc prolongation compared with administering paliperidone alone.</td>
<td></td>
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</tr>
</tbody>
</table>

* Generic available
+ XR, extended-release
** While paliperidone 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 paliperidone alone.

No long-acting injectable antipsychotic formulations are FDA-approved for use in children and adolescents.

March 2016
(Tables Updated July 2016)
### 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>
<tbody>
<tr>
<td>Chlorpromazine*</td>
<td>Thorazine®</td>
<td>• Age &gt; 6 months: 0.25 mg/lb every 4-6 hours, as needed</td>
<td>• Age &lt; 5 years: 40 mg/day</td>
<td>Approved for treatment of severe behavioral problems (age 6 months-12 years)</td>
<td>One to six times daily</td>
<td>Same as Second Generation Antipsychotics</td>
<td>None related to youth</td>
<td>• Tardive Dyskinesia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Adolescents: 10-25 mg/dose every 4-6 hours</td>
<td>• Age 5-12 years: 75 mg/day</td>
<td>• Outpatient Children: 0.55 mg/kg every 4-6 hours, as needed</td>
<td></td>
<td></td>
<td></td>
<td>• Neuroleptic Malignant Syndrome</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Age &gt; 12 years: 800 mg/day</td>
<td>• Inpatient Children: 500 mg/day</td>
<td></td>
<td></td>
<td></td>
<td>• Leukopenia, neutropenia, and agranulocytosis</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td>Approved for the management of manifestations of Psychotic Disorders (age &gt; 12 years): 1000 mg/day</td>
<td></td>
<td></td>
<td></td>
<td>• Drowsiness</td>
</tr>
<tr>
<td>Haloperidol*</td>
<td>Haldol®</td>
<td>• Age 3-12 years weighing</td>
<td>• Age 3-12 years: 0.15 mg/kg/day or 6 mg/day, whichever is less</td>
<td>Approved for treatment of Psychotic Disorders, Tourette's Disorder, and severe behavioral problems (age ≥3 years):</td>
<td>One to three times daily</td>
<td></td>
<td>None related to youth</td>
<td>• Orthostatic hypotension</td>
</tr>
<tr>
<td></td>
<td></td>
<td>○ 15-40 kg: 0.025-0.05 mg/kg/day</td>
<td>• Age ≥12 years</td>
<td>• Psychosis: 0.15 mg/kg/day</td>
<td></td>
<td></td>
<td></td>
<td>• EKG changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>○ ≥ 40 kg: 1 mg/day</td>
<td>○ Acute agitation: 10 mg/dose</td>
<td>• Tourette’s Disorder and severe behavioral problems: 0.075 mg/kg/day</td>
<td></td>
<td></td>
<td></td>
<td>• Extrapyramidal symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Age &gt; 12: 1 mg/day</td>
<td>○ Psychosis: 15 mg/day</td>
<td>• Severely disturbed children: 6 mg/day</td>
<td></td>
<td></td>
<td></td>
<td>• Ocular changes</td>
</tr>
<tr>
<td>Perphenazine*</td>
<td>Trilafon®</td>
<td>• Age 6-12 years: Insufficient Evidence</td>
<td>• Age 6-12 years: Insufficient Evidence</td>
<td>Approved for treatment of Psychotic Disorders (age ≥12 years):</td>
<td>Two to four times daily</td>
<td></td>
<td>None related to youth</td>
<td>• Anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Age &gt; 12 years: 4-16 mg two to four times daily</td>
<td>• Age &gt; 12 years: 64 mg/day</td>
<td>• Outpatient: 24 mg/day</td>
<td></td>
<td></td>
<td></td>
<td>• Risk of prolonged QTc interval and torsades de pointes (particularly with pimozide)</td>
</tr>
<tr>
<td>Pimozide</td>
<td>Orap®</td>
<td>Age ≥7 years: 0.05 mg/kg</td>
<td>• Age 7-12 years: 6 mg/day or 0.2 mg/kg/day, whichever is less</td>
<td>Approved for treatment of Tourette’s Disorder (age ≥12 years): 10 mg/day or 0.2 mg/kg/day, whichever is less</td>
<td>Once or twice daily</td>
<td></td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Drug (generic)</td>
<td>Drug (brand)</td>
<td>Initial Dosage</td>
<td>Target Dosage Range</td>
<td>Literature Based Maximum Dosage</td>
<td>FDA Approved Maximum Dosage for Children and Adolescents</td>
<td>Schedule</td>
<td>Patient Monitoring Parameters</td>
<td>Black Box Warning</td>
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</tr>
<tr>
<td>Carbamazepine</td>
<td>Tegretol®</td>
<td>Age 4-5: 10-20 mg/kg/day</td>
<td>Age ≥ 8 years: 300 mg/day</td>
<td>Approved for treatment of Seizure Disorders in all ages</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>Aplastic anemia</td>
</tr>
<tr>
<td>EPS (lab)</td>
<td>Tegretol®/LXP (tab, oral suspension, chewable)</td>
<td>Age 6-12: 10 mg/kg/day or 200 mg/day</td>
<td>Age 13-15: 1000 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Equetro®</td>
<td>Age ≥ 13 years: 1200 mg/day</td>
<td>Age ≥ 13 years: 1200 mg/day</td>
<td>Approved for treatment of Seizure Disorders in all ages</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>Aplastic anemia</td>
</tr>
<tr>
<td>Depakote®</td>
<td>Divalproex Sodium</td>
<td>Age 4-12: 800-800 mg/day</td>
<td>Age ≥6 years: 800-1200 mg/day</td>
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<td></td>
</tr>
<tr>
<td>Depakote® ER extended-release tablets</td>
<td>Divalproex sodium</td>
<td>Age 12 years: 1500 mg/day</td>
<td>Age ≥12 years: 1200 mg/day</td>
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</tr>
<tr>
<td>Epitol®</td>
<td>Equetro® (extended release capsule)</td>
<td>Age ≥13 years: 1200 mg/day</td>
<td>Age ≥15 years: 1200 mg/day</td>
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<td></td>
</tr>
<tr>
<td>Lithobid®</td>
<td>Eskalith®</td>
<td>Age 6-11 years: 15-20 mg/kg/day</td>
<td>Age ≥6 years: 1.2 mg/mL or 1800 mg</td>
<td>Approved for treatment of manic episodes and maintenance of Bipolar Disorder (age ≥ 12 years)</td>
<td>One to four times daily</td>
<td>EKG — baseline, yearly and as clinically indicated</td>
<td>Toxicity above therapeutic serum levels</td>
<td></td>
</tr>
<tr>
<td>Eskalith®/CR</td>
<td>Lithobid®(ER)</td>
<td>Age ≥6 years: 12 hour post dose serum level: 0.6-1.2 mg/mL</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Lithobid®</td>
<td>Eskalith®</td>
<td>Age ≥6 years: 12 hour post dose serum level: 0.6-1.2 mg/mL</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithobid®(ER)</td>
<td>Eskalith®</td>
<td>Age ≥6 years: 12 hour post dose serum level: 0.6-1.2 mg/mL</td>
<td></td>
<td></td>
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<td></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 for Children and Adolescents</th>
<th>FDA Approved Maximum Dosage for Seizure Disorders</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: 25 mg/day (increase by 25 mg every 2 weeks)</td>
<td>Approved for adjunctive therapy for Seizure Disorders: Age 2-12: 400 mg/day; Age &gt;12: 500 mg/day (use &gt;200 mg/day in adults for bipolar depression has not conferred additional efficacy)</td>
<td>Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established</td>
<td>Once or twice daily</td>
<td>CBC – baseline and as clinically indicated</td>
<td>None</td>
<td>• Dermatological reactions</td>
</tr>
<tr>
<td>Oxcarbazepine*</td>
<td>Trileptal®</td>
<td>Monotherapy (based on weight): 20-34.9 kg: 600-900 mg/day 25-34.9 kg: 900-1200 mg/day 35-44.9 kg: 900-1500 mg/day 45-49.9 kg: 1000-1500 mg/day 50-59.9 kg: 1200-1800 mg/day 60-69.9 kg: 1200-2100 mg/day ≥70 kg: 1500-2100 mg/day</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 1000 mg/day</td>
<td>Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established</td>
<td>CBC with differential – baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated</td>
<td>Twice daily</td>
<td>Pregnancy Test – baseline and as clinically indicated</td>
<td>None</td>
<td>• Hyponatremia (incidence may be as high as 24% in children)</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)
### Sedatives/Hypnotics

<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 | • Drowsiness  
• Dizziness  
• Dry mouth  
• Nausea  
• Nervousness  
• Blurred vision  
• Diminished mental alertness  
• Paradoxical excitation  
• Respiratory disease  
• Hypersensitivity reactions  
• May lower seizure threshold (avoid in epilepsy) |
| 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  
• Serotonin Syndrome  
• Contraindicated for use within 14 days of an MAOI  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• QT prolongation and risk of sudden death  
• Orthostatic hypotension and syncope  
• Abnormal bleeding  
• Priapism  
• Hypeprolactinemia  
• Cognitive and motor impairment |
| Eszopiclone | Lunesta® | Insufficient Evidence | Insufficient Evidence | Not approved for children or adolescents | Once at bedtime | None | • Complex sleep behaviors possible  
• Abnormal thinking and behavior changes  
• Withdrawal effects  
• Drug abuse and dependence  
• Tolerance |
| 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 6-11 years: 0.15 mg/kg or 6 mg, 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 | • Sedation  
• May adversely affect gonadal development  
• Should be given directly before onset of sleep is desired due to short half-life |
| Ramelteon | Rozerem® | Insufficient Evidence | Insufficient Evidence | Not approved for children or adolescents | Insufficient Evidence | None | • Hypersensitivity reactions  
• Need to evaluate for comorbid diagnoses  
• Abnormal thinking and behavioral changes  
• CNS depression  
• Decreased testosterone  
• Hyperprolactinemia |
| 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  
• Age ≤6 years: 50 mg/day in divided doses  
• Age >6 years: 50-100 mg/day in divided doses | 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 | • Drowsiness  
• Dry mouth  
• Involuntary motor activity  
• Blurred vision, dizziness, diminished mental alertness  
• Paradoxical excitation associated with a small but definite risk of QT interval prolongation and torsades de pointes |

* 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)


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_Referral_or_Consultation_with_a_CAP.aspx
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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