Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care

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September 2013
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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. Establishment of rapport may be difficult. These multiple factors serve to complicate diagnosis. Foster children may reside in areas of the state where mental health professionals such as child psychiatrists are not readily available. Similarly, caregivers and health providers may be faced with critical situations that require immediate decisions about the care to be delivered. For these and other reasons, a need exists for treatment guidelines and parameters regarding the appropriate use of psychotropic medications for children and youth in foster care.

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. 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. 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.

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, inadequate numbers 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 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. A useful toolkit (American Academy of Pediatrics Task Force on Mental Health Addressing Mental Health Care in Primary Care: A Clinicians Toolkit) can be found at: www.aap.org/pcorss/demos/mht.html

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.
- Youth, as well as caregivers, should be involved in decision-making about treatment, in accordance with their developmental level.
- 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 other 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, it should occur in a systematic orderly process, accompanied by on-going monitoring, evaluation, and documentation. The treatment goal is 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 number of prn doses in a day and a week. The frequency of administration should be monitored to assure that these do not become regularly scheduled medications.
- The frequency of clinician follow-up

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with the patient 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 experienced meaningful improvement within a timeframe that is appropriate for the child’s clinical response and the medication regimen being used.

- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, 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 nonpsychotic 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, 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.

**Therapeutic Controversies**

**Antipsychotic selection**

Significant controversy exists regarding the use of 2nd generation versus 1st generation antipsychotics. Most of the data supporting no difference in efficacy between these two groups of antipsychotics comes from studies conducted in chronically ill adults with schizophrenia. Most of the controlled studies of the use of antipsychotics to treat...
behavioral disorders in children have been performed with 2nd generation antipsychotics, with the most evidence for risperidone. The only study comparing a 1st generation antipsychotic versus 2nd generation antipsychotics in youth was conducted in individuals with early onset schizophrenia. The 1st generation agent used in this study was molindone, an antipsychotic, no longer on the market, that is known to be weight neutral or cause weight loss in adults. It is unknown how the results of this study can be extrapolated to the treatment of children with other first generation antipsychotics.

Antipsychotics vary with regard to their side effect profiles, and side effects are the primary basis for individual medication choice. Second generation antipsychotics are prone to cause significant weight gain in many children, but the risk for the development of weight gain in youth varies significantly among the 2nd generation agents. In a systematic review (De Hert 2011) of 31 short-term randomized controlled trials including 3595 youth, the average weight gain was olanzapine (3.78 kg, 3.4 weeks), risperidone (2.37 kg, 7.5 weeks) quetiapine (2.15 kg, 4.5 weeks), aripiprazole (1.04 kg, 6.1 weeks), and ziprasidone (0.49 kg, 5.3 weeks). Significant weight gain was more common in children with autistic disorder who were younger and more likely first-time antipsychotic users. In addition, the most significant effects on glucose and lipids are associated with the 2nd generation antipsychotics known to cause the largest weight gain. Because of the risk of obesity and metabolic dysfunction associated with some of the 2nd generation antipsychotics, particularly olanzapine, clinicians should consider being proactive and implement diet counseling and exercise programs at the same time that antipsychotics are initiated.

First generation antipsychotics are prone to causing extrapyramidal side effects. In particular, youth are especially susceptible to developing acute dystonic reactions from 1st generation antipsychotics. Similarly, 1st generation antipsychotics pose a higher risk for the development of tardive dyskinesia in chronically treated individuals. If antipsychotics are indicated, the clinician should carefully evaluate the individual needs of the child, actively engage the family in decision-making, evaluate overall benefit to risk ratio, and when indicated, choose the antipsychotic that the clinician thinks will be best tolerated by that child.

**Psychotropic medication choice in acute mania**

Traditionally, because of a lack of research, clinicians have used the same medications to treat mania associated with bipolar disorder in children and adolescents as are used in adults. Recently studies addressing the treatment of mania and mixed mania in children and adolescents have been conducted. The Treatment of Early Age Mania (TEAM) study (Geller 2012) evaluated the relative efficacy and tolerability of risperidone, lithium, and divalproex in 279 medication naïve children and adolescents with either mania or mixed mania. Risperidone was superior in efficacy to either lithium or divalproex. The discontinuation rate was higher with lithium, suggesting better tolerability with risperidone. However, risperidone did have significant adverse effects including weight gain, BMI increase, and hyperprolactinemia.

**Depression, Suicidality, and Antidepressants**

In October 2003, the FDA released a public health advisory alerting health care professionals to reports of suicidality (suicidal verbalizations and suicidal behaviors) in clinical trials of antidepressants in pediatric populations. These reports provided the impetus for a FDA meta-analytic review of short-term clinical trials of antidepressants in children and adolescents. These analyses involved review, assessment, and reclassification of over 400 case descriptions. This review ultimately resulted in findings of an increased risk of suicidality during the first few weeks of antidepressant treatment. The FDA responded by issuing a black box warning in October 2004. The black box warning describes an increased risk of suicidality (suicidal behavior and ideation) for ALL antidepressants used in individuals under the age of 18. The incidence of suicidal ideations and behaviors in these pooled analyses was about 4% for those youth receiving antidepressants compared with 2% on placebo. It is important to note that no completed suicides (i.e., deaths) were reported in any of these trials.

The mortality risk of depression is from suicide. Other major suicide risk factors that should be assessed include: anxiety, substance abuse, and conduct disorders, life stressors (such as legal or disciplinary/school problems), interpersonal losses, family and peer discord, abuse, lack of support, poor interpersonal problem-solving ability, the tendency to respond with hostility or overt aggression to frustration or stress, hopelessness and cognitive distortions. All youth with depression should be monitored carefully for the potential presence of suicidal thoughts or behaviors. This should occur at the time of initial clinical assessment and upon each visit follow-up until depression is no longer present. Assessment of suicidality should include asking questions about ideation and frequency, plans, intention, means, and potential dangerousness. More frequent visits, combined with follow-up calls as necessary, should be considered along with appropriate review of safety plans. It is noteworthy that in one study, the concomitant use of cognitive behavioral therapy was shown to decrease the incidence of suicidality associated with SSRI use.

**Stimulants and growth**

Parents and caregivers are often concerned about the possibility that stimulants may adversely affect growth. This is largely related to the fact that, at least short term, stimulants decrease appetite. Although data from different studies are mixed, results from the Multimodal Treatment of ADHD (MTA) study, indicate that weight loss occurred during the first 3-4 months of treatment, but this was followed be a resumption of weight increase. The rate of growth in height decreased by about 1-3 cm/year over the first 1-3 years of medication treatment. These decreases in height were only seen in the youth who were adherent with their stimulant medications. Although both advantages and disadvantage-
es are associated with medication holidays or vacations, this has been suggested as one mechanism to minimize potential effects on growth. It is questionable whether the use of stimulants has any effect on ultimate adult height (Swanson 2008; Vitello 2008).

**Stimulants and cardiovascular side effects**

Both stimulants and atomoxetine cause small but statistically significant increases in blood pressure and pulse rate. However, it is unclear whether these changes are clinically significant. Although case reports of sudden death in children taking stimulants have been reported, a causal link has not been proven. A large cohort study using data from a 5-state Medicaid database [1999-2003] and the 14-state HealthCore Integrated Research Database [2001-2006] with 241,417 incident users found no statistically significant difference between incident users and nonusers in the rate of sudden death, ventricular arrhythmia, or death from any cause. One theory is that underlying cardiac disorders such as serious structural abnormalities, cardiomyopathies, serious heart rhythm disturbances, or other serious cardiac problems may place children at increased risk of sudden death when stimulants are administered. The clinician should conduct a careful history of the child and the family regarding potential heart problems. A thorough physical exam should also be conducted. If the history and physical provide suspicion of a cardiac problem, then an electrocardiogram should be considered before beginning a stimulant. Although not routinely required, if the child has a known history of a cardiac problem, then a cardiology consult should be considered before beginning a stimulant (Cooper 2011, Correll 2011, Perrin 2008, Skelleman 2011).

**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 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 report information regarding 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 black box outlining the information at the very beginning of the product labeling, and have, in turn, been named black box warnings. Black box warnings are the strongest warning required by the FDA. It is important for clinicians to be familiar with all medication adverse effects, including black box warnings, in order to appropriately monitor patients and minimize the risk of their occurrence.

The FDA has in recent years taken additional measures to try and help patients avoid serious adverse events. New guides called Medication Guides have been developed, and are specific to particular drugs and drug 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. FDA requires that Medication Guides be issued with certain prescribed drugs 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 preferred drug list of medications potentially prescribed for foster children is the same as for all other Texas Medicaid recipients.

These are intended to serve as a guide 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, and individual patient 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 observed.

Not all medications prescribed by clinicians for psychiatric diagnoses in children and adolescents are included below. 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 14.**
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 stimulant and an immediate release stimulant of the same chemical entity (e.g., methylphenidate) 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 mono-therapy.

6. The psychotropic medication dose exceeds usual recommended doses (FDA and/or literature based maximum dosages).

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
   - Antipsychotics: Less than four (4) years of age
   - Mood Stabilizers: Less than four (4) 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.
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October 2013

Committee Members Disclosures: Since September 1, 2007, the authors below disclose the following financial relationships:

Dr. Allison has served as a member of the speakers’ bureaus for Watson Pharmaceuticals, Novartis, and Abbott Pharmaceuticals, and he has received grant support through his employer institution from BIPI, Bristol Myers Squibb, Forest, Glaxo Smith Kline, Juergeren, Novartis, Oresigen, and Pfizer Pharmaceuticals.

Dr. Crismon has received grant support through his employer institution from Shire Pharmaceuticals. He has served as an expert witness for the U.S. Department of Justice.

Dr. Kratochvil has received royalties from Oxford Press, and through his employer institution he has received support for serving as a consultant for AstraZeneca, Abbott, Lilly, Pfizer, Quintiles, and Theravance. He has received grant support through his employer institution from Abbott, AstraZeneca, Forest, Lilly, Pfizer, Seaside, and Shire Pharmaceuticals, and through his employer institution he has received support for serving on the Data Safety Monitoring Boards for Otsuka, Pfizer and Seaside Pharmaceuticals.

Dr. Lopez holds stock in Lilly, Merck, Proctor & Gamble, and Pfizer Pharmaceuticals.

Dr. Pliszka has received speaking honoraria from Janssen/Ortho McNeil, he has served as a consultant for Shire Pharmaceuticals, and he has served as an expert witness for Eli Lilly Pharmaceuticals. He has received research grants through his employer institution from Janssen/Ortho McNeil and Shire Pharmaceuticals.

The other members of the working group do not have any financial relationships to disclose.
References


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_Solicit_Referral_or_Consultation_with_a_CAP.aspx

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## 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>Black Box Warning**</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
</table>
| Amphetamine mixed salts* | Adderall®    | • Age 3-5 years: 2.5 mg/day  
                           • Age ≥ 6 years: 5-10 mg/day | >50 kg: 60 mg/day             | Approved for children 3 years and older: 40 mg/day       | One to three times daily |                     | • Sudden death in those with pre-existing structural cardiac abnormalities or other serious heart problems |
|                          | Adderall®XR  | • Age 6-12 years: 5-10 mg/day  
                           • Age ≥13 years: 10 mg/day   |                               | Approved for children 6 years and older: 30 mg/day       | Once daily |                     |                                                                                          |
| Dextroamphetamine*       | Dexedrine®   | • Age 3-5 years: 2.5 mg/day  
                           • Age ≥ 6 years: 5 mg twice daily | >50 kg: 60 mg/day             | Approved for children 6 years and older: 40 mg/day       | Once or twice daily |                     |                                                                                          |
|                          | Dexedrine®Spansule® | • Age ≥ 6 years: 5 mg/day |                               |                                                           |          |                     |                                                                                          |
| Lisdexamfetamine          | Vyvanse®     | 30 mg/day        | 70 mg/day                     | Approved for children 6 years and older: 70 mg/day       | Once daily |                     | • Abuse potential  
                           • Sudden death and serious cardiovascular events  
                           • Hypertension  
                           • Psychiatric adverse event  
                           • Long-term suppression of growth  
                           • Tics  
                           • Decreased appetite  
                           • Sleep disturbance |
| Methylphenidate*          | Ritalin®     | • Age 3-5 years: 2.5 mg twice daily  
                           • Age ≥ 6 years: 5 mg twice daily |                               | Approved for children 6 years and older: 60 mg/day       | One to three times daily |                     |                                                                                          |
|                          | Ritalin®SR   | 20 mg/day        |                               |                                                           | 1-2 X daily |                     |                                                                                          |
|                          | Ritalin®LA   | 20 mg/day        |                               |                                                           | Once daily |                     |                                                                                          |
|                          | Metadate®ER  | 10 mg/day        |                               | Approved for children 6 years and older: 60 mg/day       | 2-3 X daily |                     |                                                                                          |
|                          | Metadate®CD  | 10 mg/day        |                               |                                                           | Once daily |                     |                                                                                          |
|                          | Methylin®    | 5 mg twice daily |                               | Approved for children 6 years and older: 60 mg/day       | One to three times daily |                     |                                                                                          |
|                          | Methylin®ER  | 10 mg/day        |                               |                                                           | 2-3 X daily |                     |                                                                                          |
|                          | Concerta®    | 18 mg/day        | 108 mg/day                    | Approved for children 6 years and older: 54 mg/day       | Once daily |                     |                                                                                          |
|                          |              |                 |                               | • Age 6-12 years: 54 mg/day  
                           • Age 13-17 years: lesser of 72 mg/day or 2 mg/kg/day |                      |                     |                                                                                          |
|                          | Daytrana®TD  | 10 mg/day        | 30 mg/day                     | Approved for children 6 years and older: 30 mg/day (largest patch) | Once daily |                     |                                                                                          |
| Dexamethylphenidate*      | Focalin®     | 2.5 mg twice daily | 50 mg/day                     | Approved for children 6 years and older: 20 mg/day       | Twice daily |                     |                                                                                          |
|                          | Focalin®XR   | 5 mg/day         |                               | Approved for children 6 years and older: 30 mg/day       | Once daily |                     |                                                                                          |

* 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
## 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>Atomoxetine</td>
<td>Strattera®</td>
<td></td>
<td>Weight ≤70 kg: 0.5 mg/kg/day</td>
<td>Lesser of 1.8 mg/kg or 100 mg/day</td>
<td>Once or twice daily</td>
<td>None</td>
<td>None</td>
<td>Suicidal thinking in children and adolescents being treated for ADHD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Weight &gt;70 kg: 40 mg/day</td>
<td>Approved for treatment of ADHD (age 6-17 years): Lesser of 1.4 mg/kg/day or 100 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FDA Approved Maximum Dosage for Children and Adolescents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clonidine®</td>
<td>Catapres® (IR)</td>
<td></td>
<td>Weight &lt;45 kg: 0.05 mg/day</td>
<td>Weight 27-40.5 kg: 0.2 mg/day</td>
<td>One to four times daily</td>
<td>Personal and family cardiovascular history</td>
<td>None</td>
<td>Hypotension, Bradycardia, Syncope, Sedation/Somatolence, Do not discontinue abruptly</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Weight &gt;45 kg: 0.1 mg/day</td>
<td>Weight 40.5-45 kg: 0.3 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Weight &gt;45 kg: 0.4 mg/day</td>
<td>Weight &gt;45 kg: 4 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kapvay® (ER)</td>
<td>0.1 mg/day</td>
<td>0.4 mg/day</td>
<td>Approved for treatment of ADHD (age 6-17 years): 0.4 mg/day</td>
<td>Once or twice daily</td>
<td></td>
<td></td>
<td>CAUTION IF USED WITH ANTIPSYCHOTICS (↓ BP)</td>
</tr>
<tr>
<td>Guanfacine®</td>
<td>Tenex® (IR)</td>
<td></td>
<td>Weight &lt;45 kg: 0.5 mg/day</td>
<td>Weight 27-40.5 kg: 2 mg/day</td>
<td>One to four times daily</td>
<td>Personal and family cardiovascular history</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Weight &gt;45 kg: 1 mg/day</td>
<td>Weight 40.5-45 kg: 3 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Weight &gt;45 kg: 4 mg/day</td>
<td>Weight &gt;45 kg: 4 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intuniv® (ER)</td>
<td>1 mg/day</td>
<td>4 mg/day</td>
<td>Approved for treatment of ADHD (age 6-17 years): 4 mg/day</td>
<td>Once daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bupropion*</td>
<td>Wellbutrin®</td>
<td>Lesser of 3 mg/ kg/day or 150 mg/day</td>
<td>Lesser of 6 mg/kg/day or 300 mg/day with no single dose &gt;150 mg</td>
<td>Not approved for children and adolescents</td>
<td>One to three times daily</td>
<td>None</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></td>
<td>Wellbutrin®SR</td>
<td>Same as above</td>
<td>400 mg/day</td>
<td>Approved treatment of depression ≥12 years: 100 mg/day</td>
<td>One or twice daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wellbutrin®XL</td>
<td>Same as above</td>
<td>450 mg/day</td>
<td></td>
<td>Once daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imipramine*</td>
<td>Tofranil®</td>
<td>Lesser of 1 mg/kg/ day or 25 mg/day</td>
<td>Lesser of 4 mg/kg/ day or 200 mg/day</td>
<td>Approved for treatment of depression ≥12 years: 100 mg/day</td>
<td>Twice daily</td>
<td>* Pulse, ECG</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Nortripyrine*</td>
<td>Aventyl®</td>
<td>0.5 mg/kg/day</td>
<td>Lesser of 2 mg/kg/ day or 100 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>Twice daily</td>
<td>* Pulse, ECG</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pamelar®</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Nortrilen®</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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>
</table>
| Citalopram*   | Celexa®       | • Children: 10 mg/day  
• Adolescents: 20 mg/day | 40 mg/day | Not approved for children and adolescents | Once daily | • Pregnancy test  
as clinically indicated  
• Monitor for emergence of suicidal ideation or behavior  
• Monitor weight and growth | 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 | • Use in combination with MAOIs  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• Serotonin Syndrome or Neuroleptic Malignant Syndrome  
• Interference with cognitive and motor performance  
• Lowers seizure threshold  
• Hyponatremia |
| Escitalopram* | Lexapro®      | • Age 6-17 years (autism): 2.5 mg/day  
• Adolescents (MDD): 10 mg/day | • Age 6-12 years: 20 mg/day  
• Age ≥ 12 years: 30 mg/day | • Not approved for children  
• Approved for treatment of MDD in adolescents (age 12-17 years): 20 mg/day | Once daily | • Pregnancy test  
as clinically indicated  
• Monitor for emergence of suicidal ideation or behavior  
• Monitor weight and growth | 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 | • Use in combination with MAOIs  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• Serotonin Syndrome or Neuroleptic Malignant Syndrome  
• Interference with cognitive and motor performance  
• Lowers seizure threshold  
• Hyponatremia |
| Fluoxetine*   | Prozac®       | • Children: 5-10 mg/day  
• Adolescents: 10 mg/day | 60 mg/day | • Approved for treatment of MDD (age 8-18 years): 20 mg/day  
• Approved for treatment of OCD (age 7-17 years): 60 mg/day | Once daily | • Pregnancy test  
as clinically indicated  
• Monitor for emergence of suicidal ideation or behavior  
• Monitor weight and growth | 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 | • Use in combination with MAOIs  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• Serotonin Syndrome or Neuroleptic Malignant Syndrome  
• Interference with cognitive and motor performance  
• Lowers seizure threshold  
• Hyponatremia |
| Paroxetine*   | Paxil®        | • Children: Not recommended  
• Adolescents: 10 mg | • Children: Not recommended  
• Adolescents: 40 mg | Not approved for children and adolescents | Once daily | • Pregnancy test  
as clinically indicated  
• Monitor for emergence of suicidal ideation or behavior  
• Monitor weight and growth | 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 | • Use in combination with MAOIs  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• Serotonin Syndrome or Neuroleptic Malignant Syndrome  
• Interference with cognitive and motor performance  
• Lowers seizure threshold  
• Hyponatremia |
| Paroxetine*   | Paxil®CR      | • Children: Not recommended  
• Adolescents: 25 mg | • Children: Not recommended  
• Adolescents: 50 mg | Not approved for children and adolescents | Once daily | • Pregnancy test  
as clinically indicated  
• Monitor for emergence of suicidal ideation or behavior  
• Monitor weight and growth | 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 | • Use in combination with MAOIs  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• Serotonin Syndrome or Neuroleptic Malignant Syndrome  
• Interference with cognitive and motor performance  
• Lowers seizure threshold  
• Hyponatremia |
| Fluvoxamine* | Luvox®        | 25 mg/day | • Age 8-11 years: 200 mg/day  
• Age 12-17 years: 300 mg/day | Approved for treatment of OCD (age 8-17 years): 200 mg/day  
• Ages 8-11 years: 200 mg/day  
• Ages 12-17 years: 300 mg/day | Daily doses >50 mg should be divided | • Pregnancy test  
as clinically indicated  
• Monitor for emergence of suicidal ideation or behavior  
• Monitor weight and growth | 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 | • Use in combination with MAOIs  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• Serotonin Syndrome or Neuroleptic Malignant Syndrome  
• Interference with cognitive and motor performance  
• Lowers seizure threshold  
• Hyponatremia |
| Fluvoxamine* | Luvox®CR      | 100 mg/day |  |  |  |  |  |  |
| Sertraline*   | Zoloft®       | Age 6-12 years: 12.5-25 mg/day  
Age 13-17 years: 25-50 mg/day | 200 mg/day | Approved for treatment of OCD (age 6-17 years): 200 mg/day | Once daily | • Pregnancy test  
as clinically indicated  
• Monitor for emergence of suicidal ideation or behavior  
• Monitor weight and growth | 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 | • Use in combination with MAOIs  
• Suicidal ideation  
• Activation of mania/hypomania  
• Discontinuation syndrome  
• Abnormal bleeding  
• Serotonin Syndrome or Neuroleptic Malignant Syndrome  
• Interference with cognitive and motor performance  
• Lowers seizure threshold  
• Hyponatremia |

* Generic available

+ CR, controlled-release

From Black Box Warning in product labeling: 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>• Children: 150 mg/day • Adolescents: 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 • Monitor for emergence of suicidal ideation or behavior • Blood pressure during dosage titration and as clinically indicated • Monitor weight and growth • Serum cholesterol levels</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>• Use in combination with MAOIs • Suicidal ideation • Abnormal bleeding • Severe skin reactions • Discontinuation syndrome • Activation of mania/hypomania • Hepatotoxicity • Orthostatic hypotension and syncope • Serotonin Syndrome or Neuroleptic Malignant Syndrome • Seizures • Elevated blood pressure • Hyponatremia</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>Cymbalta®</td>
<td>• Children: Insufficient Evidence • Adolescents: 40 mg/day</td>
<td>• Children: Insufficient Evidence • Adolescents: 60 mg/day</td>
<td>Not approved for children and adolescents</td>
<td>Once or twice daily</td>
<td>• Pregnancy test – as clinically indicated • Monitor for emergence of suicidal ideation or behavior • Blood pressure prior to initiating treatment, during dosage titration and as clinically indicated • Hepatic function testing – baseline and as clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desvenlafaxine</td>
<td>Pristiq®</td>
<td>• Children: Insufficient Evidence • Adolescents: 50 mg/day</td>
<td>• Children: Insufficient Evidence • Adolescents: 100 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 prior to initiating treatment, during dosage titration and as clinically indicated • Hepatic function testing – baseline and as clinically indicated • Serum cholesterol and triglyceride levels</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Generic Available

+ XR, extended-release

From Black Box Warning on package inserts: 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.
## 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>Arpiprazole</td>
<td>Abilify®</td>
<td>2 mg/day</td>
<td></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>Not approved for depression in under age 10. Increased the risk of suicidal thinking and behavior in short-term studies in children and adolescents with major depressive disorder and other psychiatric disorders.</td>
<td>Neuroleptic Malignant Syndrome</td>
</tr>
<tr>
<td>Quetiapine*</td>
<td></td>
<td></td>
<td></td>
<td>• Approved for treatment of Bipolar Mania (age 10-17 years): 600 mg/day</td>
<td>Two to three times daily</td>
<td>• CBC as indicated by guidelines approved by the FDA in the product labeling.</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Clozapine*</td>
<td></td>
<td></td>
<td></td>
<td>• Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 800 mg/day</td>
<td>Once daily</td>
<td>• Pregnancy test – as clinically indicated</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Olanzapine*</td>
<td>Zyprexa®</td>
<td>Age &lt; 8 years: 1.25 mg/day</td>
<td>Age 6-12 years: 2.5 mg/day</td>
<td>Age ≥ 13 years: 5.6 mg/day</td>
<td>Children: 12.5 mg/day Adolescents: 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>None related to youth</td>
<td>Neuroleptic Malignant Syndrome</td>
</tr>
<tr>
<td>Risperidone*</td>
<td>Risperdal®</td>
<td></td>
<td></td>
<td>• Approved for treatment of Schizophrenia (age 13-17 years) and Bipolar Mania or Mixed Episodes (age 10-17 years): 6 mg/day</td>
<td>Once or twice daily</td>
<td>• Blood pressure, pulse rate, weight, and BMI measurement – when a new antipsychotic is initiated and at every visit.</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Clozapine*</td>
<td>Fazoclor® (oral disintegrating tablet)</td>
<td>Children: 6.25-12.5 mg/day</td>
<td>Adolescents: 6.25-25 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>None related to youth</td>
<td>None related to youth</td>
<td>Hyperprolactinemia (Except not reported with Aripiprazole, Clozapine, and Asenapine)</td>
</tr>
<tr>
<td>Asenapine (sublingual)</td>
<td>Saphris®</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Not approved for children and adolescents</td>
<td>Insufficient evidence; nothing by mouth for 10 minutes after sublingual administration</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Iloperidone</td>
<td>Fanapt®</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Not approved for children and adolescents</td>
<td>Not approved for children and adolescents</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Paliperdone</td>
<td>Invega®</td>
<td>Children: Insufficient evidence</td>
<td>Adolescents: 3 mg/day</td>
<td>Insufficient evidence</td>
<td>Approved for treatment of Schizophrenia (age 12-17 years):</td>
<td>Insufficient Evidence</td>
<td>Tardive Dystonias evaluation – every 12 months. For high risk patients (Including the elderly), every 6 months.</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Ziprasidone*</td>
<td>Geodon®</td>
<td>Bipolar Disorder (age 10-17 years): 20 mg/day</td>
<td>Tourette’s Disorder: 5 mg/day</td>
<td>Bipolar Disorder: Weight ≤ 45 kg: 80 mg/day</td>
<td>Insufficient evidence; take with ≥500 calorie meal</td>
<td>Insufficient evidence; take with &gt;350 calorie meal</td>
<td>None related to youth</td>
<td>None related to youth</td>
</tr>
<tr>
<td>Lamisilodone</td>
<td>Latuda®</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Not approved for children and adolescents</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
### 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>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  
Approved for the management of manifestations of Psychotic Disorders (age > 12 years): 1 g/day | One to six times daily | None related to youth | • Tardive Dyskinesia  
• Neuroleptic Malignant Syndrome  
• Leukopenia, neutropenia, and agranulocytosis  
• Drowsiness  
• Orthostatic hypotension  
• EKG changes  
• Extrapyramidal symptoms |
| Haloperidol* | Haldol® | • Age 3-12 years,  
(15 – 40 kg): 0.025-0.05 mg/kg/day  
• Age ≥13 years: 1 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 | |
| Perphenazine* | Trilafon® | • Children: insufficient evidence  
• Adolescents:  
  ○ Outpatient: 4-8 mg three times daily  
  ○ Inpatient: 8-16 mg twice to four times daily  
• Adolescents: 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 | • Ocular changes  
• Hyperprolactinemia  
• Anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention)  
• Antiemetic effect (Reported in Chlorpromazine and Perphenazine) |
| Pimozide | Orap® | Age ≥7 years: 0.05 mg/kg  
• Age 7-12 years: lesser of 6 mg/day or 0.2 mg/kg/day  
• Age ≥ 12 years: Lesser of 10 mg/day or 0.2 mg/kg/day | Approved for treatment of Tourette's Disorder  
(age ≥12 years):  
Lesser of 10 mg/day or 0.2 mg/kg/day | Once or twice daily | None related to youth | |

* Generic available
# 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</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>Carbamazepine*</td>
<td>Carbamazepine ER</td>
<td>- Age &lt; 6 years: 10-20 mg/kg/day</td>
<td>- Age &lt;6 years: 35 mg/kg/day</td>
<td>- Age &lt;6 years: 35 mg/kg/day</td>
<td>Approved for treatment of Seizure Disorders in all ages</td>
<td>Twice daily</td>
<td>HLA-B*1502 Allele (risk of SJS)</td>
<td>Stevens-Johnson Syndrome</td>
<td>Aplastic Anemia/granulocytosis</td>
</tr>
<tr>
<td>Tegretol®</td>
<td>Tegretol®</td>
<td>- Age 6-12 years: 10 mg/kg/day or 200 mg/day</td>
<td>- Age 6-12 years: 800-1200 mg/day</td>
<td>- Age 12-15 years: 1000 mg/day</td>
<td>- Age &gt;15 years: 1200 mg/day</td>
<td>Two to four times daily</td>
<td>Pregnancy test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tegretol®XR</td>
<td>Tegretol®XR</td>
<td>- Age &gt;12 years: 400 mg/day</td>
<td>- Age &gt;12 years: 800-1200 mg/day</td>
<td>- Age &gt;15 years: 1200 mg/day</td>
<td></td>
<td>Twice daily</td>
<td>CBC</td>
<td>Electrolytes</td>
<td></td>
</tr>
<tr>
<td>Divalproex Sodium*</td>
<td>Depakote®</td>
<td>10-15 mg/kg/day</td>
<td>30-60 mg/kg/day</td>
<td>Serum level: 125 µg/mL or 60 mg/kg/day</td>
<td>Approved for treatment of Seizure Disorders (age ≥ 10 years)</td>
<td>One to three times daily</td>
<td>Chemistry Panel</td>
<td>CBC (with platelets)</td>
<td>Hepatotoxicity · Pancreatitis</td>
</tr>
<tr>
<td>Lithium*</td>
<td>Eskalith®</td>
<td>Children: Lesser than 15-20 mg/kg/day or 150 mg twice per day</td>
<td>Dose adjustment based upon serum level</td>
<td>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>One to four times daily</td>
<td>Chemistry Panel</td>
<td>CBC (with platelets)</td>
<td>Toxicity above therapeutic serum levels</td>
</tr>
<tr>
<td>Lithiodi®(ER)</td>
<td>Lithiodi®(ER)</td>
<td>Adolescents: Lesser than 15-20 mg/kg/day or 300 mg twice per day</td>
<td></td>
<td>Serum level: 0.6-1.2 mEq/L</td>
<td>Maximum dose based upon serum level: 50-100 µg/mL or 60 mg/kg/day</td>
<td>One to three times daily</td>
<td>Serum Chemistry</td>
<td>LFTs</td>
<td>Acute kidney injury · Chronic renal function impairment · Special risk patients: those with significant renal or cardiovascular disease, severe dehydration, dehydration, or sodium depletion · Polyuria · Tinnitus · Diarrhea · Nausea · Hypothyroidism · Teratogenicity</td>
</tr>
<tr>
<td>Lamotrigine*</td>
<td>Lamicta®</td>
<td>Children: 2-5 mg/day</td>
<td>Monotherapy: 4.5-7.5 mg/kg/day or 1 mg/kg/day</td>
<td>With Valproate: 1-3 mg/kg/day</td>
<td>Approved for adjunctive therapy for Seizure Disorders: Age ≥ 2-12: 400 mg/day</td>
<td>Once or twice daily</td>
<td>Pregnancy test</td>
<td></td>
<td>Serious rashes including Stevens-Johnson syndrome</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adolescents: 25 mg/day (increase by 25 mg every 2 weeks)</td>
<td>Monotherapy: 225-375 mg/day or 100 mg/kg/day</td>
<td>With Valproate: 100-200 mg/day</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>With Valproate and EIAEDs®</td>
<td>100-400 mg/day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxcarbazepine*</td>
<td>Trileptal®</td>
<td>8-10 mg/kg/day</td>
<td>Monotherapy (based on weight): 20-24 mg/kg</td>
<td>35-44.9 mg/kg</td>
<td>Approved for treatment of Seizure Disorders as monotherapy (age ≥ 4 years), or as adjunctive therapy in (age ≥ 2 years):</td>
<td>Twice daily</td>
<td>CBC</td>
<td>Electrolytes</td>
<td>Hypotension · Anaphylactic reactions and angioedema · Patients with a past history of hypersensitivity reaction to carbamazepine · Serious dermatological reactions · Withdrawal seizures · Cognitive-neuropsychiatric adverse events · Multi-organ hypersensitivity · Hematologic events</td>
</tr>
</tbody>
</table>

* Generic Available
* EIAED’s - Enzyme Inducing Anti-Epileptic Drugs (e.g. Carbamazepine, Phenytoin, Primidone)
+ ER and XR, extended-release; CR, controlled release
## 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 5-12 years: 12.5-25 mg  
• Age ≥12 years: 25-50 mg | • 25-77 lbs: 12.5 mg  
• 38-49 lbs: 19 mg  
• 50-99 lbs: 25 mg  
• ≥100 lbs: 50 mg | Approved for treatment of insomnia (age ≥12 years): 50 mg at bedtime | Once at bedtime |  
|  |  |  |  |  |  |  |  |
| Trazodone* | Desyrel® | • Children: Insufficient Evidence  
• Adolescents: 25 mg | • Children: Insufficient Evidence  
• Adolescents: 100 mg/day | Not approved for children or adolescents | 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 |  |  |
| Melatonin |  | • Age 3-6 years: 0.5mg  
• Age 26 years: 1mg | • Age 3-6 years: Lesser of 0.15 mg/kg or 3 mg  
• Age 26 years: Lesser of 0.15mg/kg or 6mg | Not FDA approved | Once at bedtime |  |  |
| Ramelteon | Rozerem® | Insufficient Evidence | Insufficient evidence | Not approved for children or adolescents | Insufficient Evidence |  |  |
| Hydroxyzine* | Vistaril® | • Age 3-6 years: 25 mg/day  
• Age 6-12 years: 50 mg  
• Age > 12 years: 100 mg | Approved as a sedative when used as a premedication and following general anesthesia: 5.6 mg/kg | Once at bedtime |  |  |  |

* Generic Available

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

Use of zolpidem in pediatric patients: Safety and effectiveness of zolpidem have not been established in pediatric patients. In an 8-week study in pediatric patients (aged 6-17 years) with insomnia associated with ADHD, zolpidem did not decrease sleep latency compared to placebo. Hallucinations were reported in 7.4% of the pediatric patients who received zolpidem; none of the pediatric patients who received placebo reported hallucinations.
Glossary

**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.

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

**ECG** = 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

Acknowledgements

**Dara Teibel, Pharm.D.** (at the time a University of Texas Pharm.D. Candidate) assisted with the literature search and updating of the medication tables.

**Richard Steinberg** (Texas Department of Assistive and Rehabilitative Services) provided final editing and design.

Web Reference for the **September 2013 Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care**

[http://www.dfps.state.tx.us/Child_Protection/Medical_Services/guide-psychotropic.asp](http://www.dfps.state.tx.us/Child_Protection/Medical_Services/guide-psychotropic.asp)