Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care

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 Therapeutics

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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. 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

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 disadvantag-

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 monotherapy.

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.

Members of the Ad Hoc Working Group on Psychotropic Medication Parameters for Children and Youth in Foster Care

M. Lynn Crismon, Pharm.D.: Dean, James T. Doluisio Regents Chair & Behrens Centennial Professor, College of Pharmacy, The University of Texas at Austin, Austin, TX. Co-Chair

James A. Rogers, M.D.: Medical Director, Texas Department of Family and Protective Services, Austin, TX. Co-Chair

D. Crawford Allison, M.D.: Clinic Physician and Research Medical Director, Hillcrest Family Health Center, Waco, TX.

Emilie Becker, M.D.: Texas Medicaid Chip Mental Health Medical Director, Texas Health and Human Services Commission, Austin, TX.

Angela Hughes Campbell, Pharm.D.: Psychopharmacologist, Austin State Hospital (Child and Adolescent Psychiatric Service), Austin, TX.

Mark Janes, M.D.: Medical Director, Bluebonnet Trails Community Services, Round Rock, TX.

Christopher J. Kratochvil, M.D.: Child Psychiatrist, Associate Vice Chancellor for Clinical Research, Chief Medical Officer UNeHealth, University of Nebraska Medical Center, Omaha, NE.

Lynn Lasky Clark: President & CEO, Mental Health America of Texas, Austin, TX.

Molly Lopez, Ph.D.: Clinical Psychologist and Research Associate Professor, The University of Texas at Austin, Austin, TX.

James Lukefahr, M.D.: Medical Director-Center for Miracles, Professor of Pediatrics-University of Texas Health Science Center-Division of Child Abuse Pediatrics, San Antonio, TX.

Octavio N. Martinez, Jr., M.D.: Executive Director-Hogg Foundation for Mental Health, The University of Texas at Austin, Austin, TX.

Nina Jo Muse, M.D.: Child Psychiatrist: Texas Department of State Health Services, and private consultation practice, Austin, TX.

Sylvia Muzquiz-Drummond, M.D.: Medical Director MHMRA of Harris County, Houston, TX.

Steven Pliszka, M.D.: Professor and Chief of the Child Psychiatry Division, Department of Psychiatry, University of Texas Health Science Center, San Antonio, TX.

Manuel Schydlower, M.D.: Professor of Pediatrics, Associate Dean for Admissions, Texas Tech University Health Sciences Center, Paul L. Foster School of Medicine, El Paso, TX.

Kathy Teutsch, R.N., LMSW-MSSW: CPS Division Administrator for Medical Services, Texas Department of Family and Protective Services, Austin, TX.

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Stimulants (for treatment of ADHD)

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning**	Warnings and Precautions
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	• Abuse potential • Sudden death and serious cardiovascular events	• Sudden death in those with pre-existing structural cardiac abnormalities or other serious heart problems • Hypertension • Psychiatric adverse event • Long-term suppression of growth • Tics • Decreased appetite • Sleep disturbance
	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		
Methylphenidate*	Ritalin®	• Age 3-5 years: 2.5 mg twice daily • Age ≥ 6 years: 5 mg twice daily	• Age 3-5 years: 22.5 mg/day • >50 kg: 100 mg/day	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: • Age 6-12 years: 54 mg/day • Age 13-17 years: lesser of 72 mg/day or 2 mg/kg/day	Once daily		
	Daytrana®TD	10 mg/day	30 mg/day	Approved for children 6 years and older: 30 mg/day (largest patch)	Once daily		
Dexmethylphenidate*	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

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Baseline/ Monitoring	Black Box Warning	Warnings and Precautions
Atomoxetine	Strattera®	• Weight ≤70 kg: 0.5 mg/kg/day • Weight >70 kg: 40 mg/day	Lesser of 1.8 mg/kg or 100 mg/day	Approved for treatment of ADHD (age 6-17 years): Lesser of 1.4 mg/kg/day or 100 mg/day	Once or twice daily	None	Suicidal thinking in children and adolescents being treated for ADHD	• Severe liver injury • Serious cardiovascular events, including sudden death, particularly in those with pre-existing structural abnormalities or other serious heart problems • Increased blood pressure and heart rate • Psychiatric adverse events • Allergic Events • Priapism • Long-term suppression of growth • Weight gain
Clonidine*	Catapres® (IR)	• Weight <45 kg: 0.05 mg/day • Weight >45 kg: 0.1 mg/day	• Weight 27-40.5 kg: 0.2 mg/day • Weight 40.5-45 kg: 0.3 mg/day • Weight >45 kg: 0.4 mg/day	Not approved for treatment of ADHD in children and adolescents	One to four times daily	Personal and family cardiovascular history	None	• Hypotension • Bradycardia • Syncope • Sedation/Somnolence • Do not discontinue abruptly **CAUTION IF USED WITH ANTIPSYCHOTICS (↓ BP)**
	Kapvay® (ER)	0.1 mg/day	0.4 mg/day	Approved for treatment of ADHD (age 6-17 years): 0.4 mg/day	Once or twice daily			
Guanfacine*	Tenex® (IR)	• Weight <45 kg: 0.5 mg/day • Weight > 45 kg: 1 mg/day	• Weight 27-40.5 kg: 2 mg/day • Weight 40.5-45 kg: 3 mg/day • Weight >45 kg: 4 mg/day	Not approved for children and adolescents	One to four times daily	Personal and family cardiovascular history	None	
	Intuniv® (ER)	1 mg/day	4 mg/day	Approved for treatment of ADHD (age 6-17 years): 4 mg/day	Once daily			
Bupropion*	Wellbutrin®	Lesser of 3 mg/kg/day or 150 mg/day	Lesser of 6 mg/kg/day or 300 mg/day with no single dose >150 mg	Not approved for children and adolescents	One to three times daily	None	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	• Use in combination with MAOIs • Suicidal ideation • Activation of mania/ hypomania • Lowers seizure threshold • Discontinuation syndrome • Caution with cardiac disease
	Wellbutrin®SR	Same as above	400 mg/day		Once or twice daily			
	Wellbutrin®XL	Same as above	450 mg/day		Once daily			
Imipramine*	Tofranil®	Lesser of 1 mg/kg/day or 25 mg/day	Lesser of 4 mg/kg/day or 200 mg/day	Approved for treatment of enuresis in children Age 6-12 years: lesser of 2.5 mg/kg/day or 50 mg/day Age ≥ 12 years: lesser of 2.5 mg/kg/day or 75 mg/day Approved treatment of depression ≥ 12 years: 100 mg/day	Twice daily	• Pulse • ECG		
Nortriptyline*	Aventyl®	0.5 mg/kg/day	Lesser of 2 mg/kg/day or 100 mg/day	Not approved for children and adolescents	Twice daily	• Pulse • ECG		
	Pamelor®							
	Nortrilen®							

* Generic available

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

Antidepressants, SSRIs

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
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 • Weight loss • 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: 20mg/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				
Fluoxetine*	Prozac®	• Children: 5-10 mg/day • Adolescents: 10 mg/day	60/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				
Paroxetine*	Paxil®	• Children: Not recommended • Adolescents: 10 mg	• Children: Not recommended • Adolescents: 40 mg	Not approved for children and adolescents				
	Paxil®CR	• Children: Not recommended • Adolescents: 25 mg	• Children: Not recommended • Adolescents: 50 mg					
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): • Ages 8-11 years: 200 mg/day • Ages 12-17 years: 300 mg/day	Daily doses >50 mg should be divided			
	Luvox®CR	100 mg/day						
Sertraline*	Zoloft®	Age 6-12 years: 12.5-25 mg/dayAge 13-17 years: 25-50 mg/day	200 mg/day	Approved for treatment of OCD (age 6-17 years): 200 mg/day	Once daily			

* 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

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Venlafaxine*	Effexor Effexor®XR	Age 7-17 years: 37.5 mg/day	• Children: 150 mg/day • Adolescents: 375 mg/day	Not approved forchildren and adolescents	IR: Two to three times daily XR: Once daily	• 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	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 • 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
Duloxetine	Cymbalta®	• Children: Insufficient Evidence • Adolescents: 40 mg/day	• Children: Insufficient Evidence • Adolescents: 60 mg/day	Not approved for children and adolescents	Once or twice daily	• 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		
Desvenlafaxine	Pristiq®	• Children: Insufficient Evidence • Adolescents: 50 mg/day	• Children: Insufficient Evidence • Adolescents: 100 mg/day	Not approved for children and adolescents	Once daily	• 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		

* 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)

Drug (generic)	Drug (brand)+	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Aripiprazole	Abilify®	2 mg/day	• Children: 15 mg/day • Adolescents: 30 mg/day	• Approved for treatment of Bipolar Mania or Mixed Episodes (age 10-17 years) and Schizophrenia (13-17 years): 30 mg/day • Approved for treatment of irritability associated with Autistic Disorder (age 6-17 years): 15 mg/day	Once daily	• Fasting plasma glucose level or hemoglobin A1c – at baseline, at 3 months, then every 6 months. • Lipid screening [total cholesterol, low-and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides]-at baseline, at 3 months, then every 6 months. • CBC as indicated by guidelines approved by the FDA in the product labeling. • Pregnancy test – as clinically indicated • Blood pressure, pulse rate, height, weight and BMI measurement – when a new antipsychotic is initiated and at every visit • Sexual function inquiry – inquire yearly for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbances in males (Priapism has been reported with Iloperidone, Risperidone and Ziprasidone). This inquiry should be done at each visit (quarterly for inpatients) for the first 12 months after starting an antipsychotic or until the medication dose is stable and then yearly. • EPS evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase. • Tardive Dyskinesia evaluation – every 12 months. For high risk patients (including the elderly), every 6 months.. • Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision-yearly. (Cataracts have been reported for Quietapine) • EKG - Baseline and as clinically indicated (QTc prolongation reported for Asenapine, Clozapine, Iloperidone, Paliperidone, Quietapine and Ziprasidone)	Not approved for depression in under age 18. Increased the risk of suicidal thinking and behavior in short-term studies in children and adolescents with major depressive disorder and other psychiatric disorders	• Neuroleptic Malignant Syndrome • Tardive Dyskinesia • Hyperglycemia and Diabetes Mellitus • Weight gain • Dyslipidemia • Orthostatic Hypotension • Leukopenia, neutropenia, and agranulocytosis • Lowers seizure threshold • Cognitive and motor impairment • Hyperthermia • Dysphagia • Hyperprolactinemia (Except not reported with Aripiprazole, Clozapine, and Asenapine) • Extrapyramidal side effects
Quetiapine*	Seroquel® Seroquel®XR (brand only)	• Age ≤ 9 years: 12.5-25 mg/day • Age 10-17 years: 50 mg/day	• Age ≤ 9 years: 400 mg/day • Age 10-17 years: 800 mg/day	• Approved for treatment of Bipolar Mania (age 10-17 years): 600 mg/day • Approved for treatment of Schizophrenia (13-17 years): 800 mg/day	Two to three times daily			
Olanzapine*	Zyprexa®	• Age < 6 years: 1.25 mg/day • Age 6-12 years: 2.5 mg/day • Age ≥ 13 years: 2.5-5 mg/day	Children: 12.5 mg/day Adolescents: 20 mg/day	Approved for treatment of Bipolar Mania or Mixed Episodes and Schizophrenia (age 13-17 years): 20 mg/day	Once daily		None related to youth	
Risperidone*	Risperdal®	• Children ○ <20 kg: 0.25 mg/day ○ >20 kg: 0.5 mg/day • Adolescents: 0.5 mg/day	• Children: 3 mg/day • Adolescents: 6 mg/day	• Approved for treatment of Schizophrenia (age 13-17 years) and Bipolar Mania or Mixed Episodes (age 10-17 years): 6 mg/day • Approved for treatment of irritability associated with autistic disorder (age 5-16 years): 3 mg/day	Once or twice daily		None related to youth	
Clozapine*	Clozaril® Fazaclo® (oral disintegrating tablet)	• Children: 6.25-12.5 mg/day • Adolescents: 6.25-25 mg/day	• Children: 150-300 mg/day • Adolescents: 600 mg/day Target serum clozapine level of 350 ng/mL for optimal efficacy	Not approved for children and adolescents	Once or twice daily		• Risk of life threatening agranulocytosis • Seizures • Myocarditis • Other adverse cardiovascular and respiratory effects	
Asenapine (sublingual)	Saphris®	Insufficient evidence	Insufficient evidence	Not approved for children and adolescents	Insufficient evidence; nothing by mouth for 10 minutes after sublingual adminis-tration		None related to youth	
Iloperidone	Fanapt®	Insufficient Evidence	Insufficient evidence	Not approved for children and adolescents	Insufficient Evidence		None related to youth	
Paliperidone	Invega®	• Children: Insufficient evidence • Adolescents: 3 mg/day	• Children: Insufficient evidence • Adolescents: ○ Weight < 51 kg: 6 mg/day ○ Weight ≥ 51 kg: 12 mg/day	Approved for treatment of Schizophrenia (age 12-17 years): • Weight < 51 kg: 6 mg/day • Weight ≥ 51 kg: 12 mg/day	Once daily		None related to youth	
Ziprasidone*	Geodon®	• Bipolar Disorder (age 10-17 years): 20 mg/day • Tourette's Disorder: 5 mg/day	• Bipolar Disorder • Weight ≤ 45 kg: 80 mg/day • Weight > 45 kg: 160 mg/day • Tourette's Disorder: 40 mg/day	Not approved for children and adolescents	Insufficient evidence; take with ≥500 calorie meal		None related to youth	
Lurasidone	Latuda®	Insufficient Evidence	Insufficient evidence	Not approved for children and adolescents	Insufficient evidence; take with >350 calorie meal		None related to youth	

* Generic available
\+ XR, extended-release

Antipsychotics: First Generation (Typical)

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning	Warnings and Precautions
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 • Ocular changes • Hyperprolactinemia • Anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention) • Antiemetic effect (Reported in Chlorpromazine and Perphenazine)
Haloperidol*	Haldol®	• Age 3-12 years, (15 – 40 kg): 0.025-0.05 mg/kg/day • Age ≥13 years: 1 mg/day	• Children: 0.15 mg/kg/day • Adolescents ○ Acute agitation: 15 mg/dose ○ Psychosis: 15 mg/day ○ Tourette's Disorder: 15 mg/day	Approved for treatment of Psychotic Disorders, Tourette's Disorder, and severe behavioral problems (age ≥3 years): • Psychosis: 0.15 mg/kg/day • Tourette's Disorder and severe behavioral problems: 0.075 mg/kg/day • Severely disturbed children: 6 mg/day	One to three times daily	None related to youth	
Perphenazine*	Trilafon®	• Children: insufficient evidence • Adolescents: ○ Outpatient: 4-8 mg three times daily ○ Inpatient: 8-16 mg twice to four times daily	• Children: insufficient evidence • 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	
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

Drug (generic)	Drug (brand)+	Initial Dosage	Target Dosage Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Baseline Monitoring	Black Box Warning	Warnings and Precautions
Carbamazepine*	Carbatrol®(ER) Tegretol® Tegretol®XR	• Age < 6 years: 10-20 mg/kg/day • Age 6-12 years: 10 mg/kg/day or 200 mg/day • Age >12 years: 400 mg/day	• Age <6 years: 35 mg/kg/day • Ages 6-12 years: 400-800 mg/day • Age >12 years: 800-1200 mg/day	• Age <6 years: 35 mg/kg/day • Ages 6-12 years: 800 mg/day • Age 12-15 years: 1000 mg/day • Age >15 years: 1200 mg/day	Approved for treatment of Seizure Disorders in all ages • Age < 6 years: 35 mg/kg/day • Age 6-15 years: 1000 mg/day • Age >15 years: 1200 mg/day	Twice daily Two to four times daily Twice daily	• HLA-B*1502 Allele (risk of SJS) • Pregnancy test • CBC • Electrolytes	• Stevens-Johnson Syndrome • Aplastic Anemia/granulocytosis	• Stevens-Johnson Syndrome • Aplastic anemia • Suicidality • Teratogenicity • Neutropenia • Hyponatremia • Induces metabolism of itself and some other drugs • Decreased efficacy of oral contraceptives • Withdrawal seizures
Divalproex Sodium*	Depakote®	10-15 mg/kg/day	30-60 mg/kg/day	Serum level: 125 µg/mL, or 60 mg/kg/day	Approved for treatment of Seizure Disorders (age ≥ 10 years) Maximum dose based upon serum level: 50-100 µg/mL, or 60 mg/kg/day	One to three times daily	• Chemistry Panel • CBC (with platelets) • LFTs • Pregnancy test	• Hepatotoxicity • Teratogenicity • Pancreatitis	• Hepatotoxicity • Pancreatitis • Urea cycle disorders • Teratogenicity • Suicidal ideation • Thrombocytopenia • Hyperammonemia • Multi-organ hypersensitivity reaction • Withdrawal seizures • Polycystic ovaries • Neutropenia
Lithium*	Eskalith® Eskalith®CR Lithobid®(ER)	• Children: Lesser of 15-20 mg/kg/day or 150mg twice per day • Adolescents: Lesser of 15-20 mg/day or 300 mg twice per day	Dose adjustment based upon serum level Serum level: 0.6-1.2 mEq/L	Serum level: 1.2 mEq/L, or 1800 mg	Approved for treatment of manic episodes and maintenance of Bipolar Disorder (age ≥ 12 years) Maximum dose based upon serum level: 1.2 mEq/L	One to four times daily	• Chemistry Panel • CBC (with platelets) • Serum Creatinine • LFTs • Pregnancy test • ECG • Blood for lithium serum levels should be drawn 10-12 hours after the last dose.	Toxicity above therapeutic serum levels	• Toxicity above therapeutic serum levels • Chronic renal function impairment • Special risk patients: those with significant renal or cardiovascular disease, severe debilitation, dehydration, or sodium depletion • Polyuria • Tremor • Diarrhea • Nausea • Hypothyroidism • Teratogenicity
Lamotrigine*	Lamictal®	• Children: 2-5 mg/day • Adolescents: 25 mg/day (increase by 25 mg every 2 weeks)	Children • Monotherapy: 4.5-7.5 mg/kg/day • With Valproate: 1-3 mg/kg/day • With Valproate and EIAEDs✦: 1-5 mg/kg/day • With EIAED's: 5-15 mg/kg/day Adolescents • Monotherapy: 225-375 mg/day • With Valproate: 100-200 mg/day • With Valproate and EIAEDs✦: 100-400 mg/day • With EIAEDs✦: 300-500 mg/day		Approved for adjunctive therapy for Seizure Disorders: Age 2-12: 400 mg/day Age >12: 500 mg/day Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established	Once or twice daily		Serious rashes including Stevens-Johnson syndrome	• Dermatological reactions • Potential Stevens-Johnson Syndrome • Multi-organ Hypersensitivity reactions and organ failure • Blood dyscrasias • Suicidal ideation • Aseptic meningitis • Concomitant use with oral contraceptives increases lamotrigine clearance • Withdrawal seizures
Oxcarbazepine*	Trileptal®	8-10 mg/kg/day	Monotherapy (based on weight): • 20-24.9 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: 1200 – 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	• Children: 60 mg/kg/day or 1500 mg/day • Adolescents: 60 mg/kg/day or 2100 mg/day	Approved for treatment of Seizure Disorders as monotherapy (age ≥ 4 years), or as adjunctive therapy in (age ≥ 2 years): 60 mg/kg/day or 1800 mg/day	Twice daily	• CBC • Electrolytes • Pregnancy test		• Hyponatremia • 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

* Generic Available

✦EIAED's - Enzyme Inducing Anti-Epileptic Drugs (e.g. Carbamazepine, Phenobarbital, Phenytoin, Primidone)

+ ER and XR, extended-release; CR, controlled release

Sedatives/Hypnotics

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning**	Warnings and Precautions
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	• 25-37 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		• Drowsiness • Dizziness • Dry mouth • Nausea • Nervousness • Blurred vision • Diminished mental alertness • Paradoxical excitation • Respiratory disease • Hypersensitivity reactions
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	• Serotonin Syndrome • Neuroleptic Malignant Syndrome • Use in combination with MAOIs • Suicidal ideation • Activation of mania/hypomania • Discontinuation syndrome • Abnormal bleeding • QT prolongation and risk of sudden death • Orthostatic hypotension and syncope • Abnormal bleeding • Priapism • Hyponatremia • Cognitive and motor impairment
Eszopiclone	Lunesta®	Insufficient Evidence	Insufficient evidence	Not approved for children or adolescents	Once at bedtime		• Psychiatric/physical disorder • Abnormal thinking and behavior changes • Withdrawal effects • Drug abuse and dependence • Tolerance
Melatonin		• Age 3-6 years: 0.5mg • Age ≥6 years: 1mg	• Age 3-6 years: • Lesser of 0.15 mg/kg or 3 mg • Age ≥6 years: Lesser of 0.15mg/kg or 6mg	Not FDA approved	Once at bedtime		• Sedation • May adversely affect gonadal development
Ramelteon	Rozerem®	Insufficient Evidence	Insufficient evidence	Not approved for children or adolescents	Insufficient Evidence		• Hypersensitivity reactions • Need to evaluate for co-morbid diagnoses • Abnormal thinking and behavioral changes • CNS depression • Decreased testosterone • Hyperprolactinemia
Hydroxyzine*	Vistaril®	• Age 3-6 years:25 mg • Age ≥6 years: 50mg	• Age 3-6 years: 25 mg/day • Age 6-12 years: 50 mg • Age > 12 years: 100 mg	Approved for treatment of anxiety and tension: • Age <6 years: 50 mg/day • Age ≥ 6 years: 50-100 mg/day Approved as a sedative when used as a premedication and following general anesthesia: 0.6 mg/kg	Once at bedtime		• Drowsiness • Dry mouth • Involuntary motor activity • Blurred vision, dizziness, diminished mental alertness • Paradoxical excitation

* 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

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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