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

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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.

Because of the complex issues involved in the lives of foster children, it is important that a comprehensive evaluation be performed before beginning treatment for a mental or behavioral disorder. Except in the case of an emergency, a child should receive a thorough health history, psychosocial assessment, mental status exam, and physical exam before prescribing a psychotropic medication. The physical assessment should be performed by a physician or another healthcare professional qualified to perform such an assessment. It is recognized that in some emergency situations, it may be in the best interest of the child to prescribe psychotropic medications before a physical exam can actually be performed. In these situations, a thorough health history should be performed to assess for significant medical disorders and past response to medications, and a physical evaluation should be performed as soon as possible. A thorough psychosocial assessment should be performed by an appropriately qualified mental health clinician (masters or doctoral level), a psychiatrist/child psychiatrist, or a primary care physician with experience in providing mental health care to children and youth. The child's symptoms and functioning should be assessed across multiple domains, and the assessment should be developmentally age appropriate. It is very important that information about the child's history, including history of trauma and current functioning be made available to the treating physician in a timely manner, either through an adult who is well-informed about the child or through a comprehensive medical record. It is critical to meet the individual needs of patients and their families in a culturally competent manner. This indicates a need to address communication issues as well as differences in perspective on issues such as behavior and mental functioning. Interpretation of clinical symptoms and decisions concerning treatment should, whenever possible, be informed by the child's developmental history of trauma, neglect or abuse and the timing of these stressors. In general, optimal outcomes are achieved with well-coordinated team based care with members of different professions (e.g., child psychiatrist, child psychologist, social worker, primary care physician, etc.) each contributing their particular expertise to the treatment plan and follow-up. Additionally, at present there are no biomarkers to assist with the diagnosis of mental disorders, and imaging (e.g., MRI) and other tests (e.g., EEG) are not generally helpful in making a clinical diagnosis of a mental disorder.

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

It is recognized that many psychotropic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. The FDA has a statutory mandate to determine whether pharmaceutical company sponsored research indicates that a medication is safe and effective for those indications that are listed in the approved product labeling. The FDA assures that information in the approved product labeling is accurate, and limits the manufacturer's marketing to the information contained in the approved labeling. The FDA does not regulate physician and other health provider practice. In fact,

the FDA has stated that it does "not limit the manner in which a practitioner may prescribe an approved drug." Studies and expert clinical experience often support the use of a medication for an "off-label" use. Physicians should utilize the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what is best for each individual patient. To that end, clear documentation of the physician's rationale in the medical record facilitates continuity of care and minimizes misinterpretation.

Role of Primary Care Providers

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

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

- A DSM-5 psychiatric diagnosis should be made before the prescribing of psychotropic medications.
- Clearly defined target symptoms and treatment goals for the use of psychotropic medications should be identified and documented in the medical record at the time of or before beginning treatment with a psychotropic medication. These target symptoms and treatment goals should be assessed at each clinic visit with the child and caregiver in a culturally and linguistically appropriate manner. Whenever possible, standardized clinical rating scales (clinician, patient, primary caregiver, teachers, and other care providers) or other measures should be used to quantify the response of the child's target symptoms to treatment and the progress made toward treatment goals.
- In making a decision regarding whether to prescribe a psychotropic medication in a specific child, the clinician should carefully consider potential side effects, including those that are uncommon but potentially severe, and evaluate the overall benefit to risk ratio of pharmacotherapy.
- Except in the case of an emergency, informed consent should be obtained from the appropriate party(s) before beginning psychotropic medication. Informed consent to treatment with psychotropic medication entails diagnosis, expected benefits and risks of treatment, including common side effects, discussion of laboratory findings, and uncommon but potentially severe adverse events. Alternative treatments, the risks associated with no treatment, and the overall potential benefit to risk ratio of treatment should be discussed.
- Whenever possible, trauma-informed, evidence-based psychotherapy, should begin before or concurrent with the prescription of psychotropic medication.
- Before starting psychopharmacological treatment in preschool-aged children even more emphasis should be placed on treatment with non-psychopharmacological interventions. Assessment of parent functioning and mental health needs, in addition to training parents in evidence-based behavior management can also reduce the need for the use of medication.
- Medication management should be collaborative. Youth, as well as caregivers, should be involved in decision-making about treatment, in accordance with their developmental level. Parents providing informed consent should be engaged, and where applicable, other caregivers, family, and child related agencies should be involved.
- During the prescription of psychotropic medication, the presence or absence of medication side effects should be documented in the child's medical record at each visit.
- Appropriate monitoring of indices such as height, weight, blood pressure, or laboratory findings should be documented.
- Monotherapy regimens for a given disorder or specific target symptoms should usually be tried before polypharmacy regimens. While the goal is to use as few psychotropic medications as can be used to appropriately address the child's clinical status, it is recognized that the presence of psychiatric comorbidities may affect the number of

psychotropic medications that are prescribed. When polypharmacy regimens are needed, addition of medications should occur in a systematic orderly process, accompanied by on-going monitoring, evaluation, and documentation. The goal remains to minimize polypharmacy while maximizing therapeutic outcomes.

- Medications should be initiated at the lower end of the recommended dose range and titrated carefully as needed.
- Only one medication should be changed at a time, unless a clinically appropriate reason to do otherwise is documented in the medical record. (Note: starting a new medication and beginning the dose taper of a current medication is considered one medication change).
- The use of "prn" or as needed prescriptions is discouraged. If they are used, the situation indicating need for the administration of a prn medication should be clearly indicated as well as the maximum dosage in a 24 hour period and in a week. The frequency of administration should be monitored to assure that these do not become regularly scheduled medications unless clinically indicated.
- The frequency of clinician follow-up should be appropriate for the severity of the child's condition and adequate to monitor response to treatment, including: symptoms, behavior, function, and potential medication side effects. At a minimum, a child receiving psychotropic medication should be seen by the clinician at least once every ninety days.
- The potential for emergent suicidality should be carefully evaluated and monitored, particularly in depressed children and adolescents as well as those initiating antidepressants, those having a history of suicidal behavior or deliberate self-harm and those with a history of anxiety or substance abuse disorders.
- If the prescribing clinician is not a child psychiatrist, referral to or consultation with a child psychiatrist, or a general psychiatrist with significant experience in treating children, should occur if the child's clinical status has not shown meaningful improvement within a timeframe that is appropriate for the child's diagnosis and the medication regimen being used.
- Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, appropriateness of medication daily dosage, accuracy of the diagnosis, the occurrence of comorbid disorders (including substance abuse and general medical disorders), and the influence of psychosocial stressors.
- If a medication has not resulted in improvement in a child's target symptoms (or rating scale score), discontinue that medication rather than adding a second medication to it.
- If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-5 non-psychotic diagnosis (e.g., conduct disorder, oppositional defiant disorder, intermittent explosive disorder), and the behavior disturbance has been in remission for six months, then serious consideration should be given to slow tapering and discontinuation of the medication. If the medication is continued in this situation, the necessity for continued treatment should be evaluated and documented in the medical record at a minimum of every six months.
- The clinician should clearly document care provided in the child's medical record, including history, mental status assessment, physical findings (when relevant), impressions, rationale for medications prescribed, adequate laboratory monitoring specific to the drug(s) prescribed at intervals required specific to the prescribed drug and potential known risks, medication response, presence or absence of side effects, treatment plan, and intended use of prescribed medications.

Use of Psychotropic Medication in Preschool Age Children

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

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

The publication includes specific guidelines and algorithm schematics developed by the PPWG to help guide treatment decisions for a number of psychiatric disorders that may present in preschool-aged children, including Attention-Deficit Hyperactivity Disorder, Disruptive Behavioral Disorders, Major Depressive Disorder, Bipolar Disorder, Anxiety Disorders, Post-Traumatic Stress Disorder, Obsessive-Compulsive Disorder, Pervasive Developmental

Disorders, and Primary Sleep Disorders. The working group's key points and guidelines are similar to the general principles regarding the use of psychotropic medication in children already detailed in this paper. However, the working group's algorithms put more emphasis on treating preschool-aged children with non-psychopharmacological interventions (for up to 12 weeks) before starting psychopharmacological treatment, in an effort to be very cautious in introducing psychopharmacological interventions to rapidly developing preschoolers.

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

Distinguishing between Levels of Warnings Associated with Medication Adverse Effects

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

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

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

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

Usual Recommended Doses of Common Psychotropic Medications

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

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

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

See Psychotropic Medication Tables beginning on page 8.

Criteria Indicating Need for Further Review of a Child's Clinical Status

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

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

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

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

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

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

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

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

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

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

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

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

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

Stimulants for treatment of ADHD

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
Amphetamine mixed salts*	Adderall® Evekeo®	• Age 3-5 years: 2.5 mg/day • Age ≥ 6 years: 5-10 mg/day	Age 3-5 years: 30 mg/day Age ≥ 6 years: >50 kg: 60 mg/day	Approved for children 3 years and older: 40 mg/day	One to three times daily	Baseline and ongoing: height, weight, heart rate, and blood pressure Baseline: Assessment using a targeted cardiac history of the child and the family, and a physical examination of the child with an EKG and/or a pediatric cardiology consult as indicated	• Abuse potential • Sudden death and serious cardiovascular events (Only boxed warning for amphetamine salts and dextroamphetamine)	• Risk of sudden death in those with pre-existing structural cardiac abnormalities or other serious heart problems • Hypertension • Potential for psychiatric adverse events (hallucinations, delusional thinking, mania, aggression, etc.) • Stimulants do not appear to affect ultimate adult height. If mild growth suppression occurs, it is likely reversible upon discontinuation of stimulant • Tics • Decreased appetite and weight • Sleep disturbance
	Adderall®XR	• Age 3-5 years: 5mg/day • 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			
Amphetamine base	Adzenys®XR-ODT (oral disintegrating tablet)	• Age ≥ 6 years: 6.3 mg/day (3.1 mg = 5 mg Adderall®XR)	Age 6-12 years: 18.8 mg/day Age 13-17 years: 12.5 mg/day	Approved for children 6 years and older: • Ages 6-12 years: 18.8 mg/day • Ages 13-17 years: 12.5 mg/day	Once daily			
	Dyanavel®XR (oral suspension)	• Age ≥6 years: 2.5-5 mg/day (2.5 mg = 4 mg Adderall®XR)	Age ≥6 years: 20 mg/day	Approved for children 6 years and older: 20 mg/day	Once daily			
Dextroamphetamine*	Dexedrine® Zenzedi® Procentra® (oral suspension)	• Age 3-5 years: 2.5 mg/day • Age ≥ 6 years: 5 mg twice daily	Age 3-5 years: 30 mg/day Age ≥ 6 years: >50 kg: 60 mg/day	Approved for children 3 years and older: 40 mg/day	Once or twice daily			
	Dexedrine Spansule®	• Age 3-5 years: 5 mg/day • Age ≥ 6 years: 5 mg/day		Age ≥ 6 years: 40 mg/day				
Lisdexamfetamine	Vyvanse®	• Age 3-5 years: 10 mg/day • Age ≥ 6 years: 30 mg/day	Age 3-5 years: 30 mg/day Age ≥ 6 years: 70 mg/day	Approved for children 6 years and older: 70 mg/day	Once daily			

(Continued on Page 9)

* Generic available

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

\+ XR, extended-release

Stimulants for treatment of ADHD (continued)

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
Methylphenidate*	Ritalin®	• Age 3-5 years: 2.5 mg twice daily • Age ≥ 6 years: 5 mg twice daily	Age 3-5 years: 20 mg/day Age ≥ 6 years: • ≤50 kg: 60 mg/day • >50 kg: 100 mg/day	Approved for children 6 years and older: 60 mg/day	One to three times daily	See above	See above	See above
	Methylin® (chewable and oral suspension)							
	Ritalin®SR	Age ≥ 3 years: 10 mg/day			Once daily			
	Methylin®ER							
	Metadate®ER							
	Ritalin®LA	• Age 3-5 years: 10 mg/day • Age ≥ 6 years: 10-20 mg/day			Once daily			
	Metadate®CD							
	Quillivant®XR (oral suspension)							
	QuilliChew®ER (chewable)							
	Aptensio®XR							
	Concerta®	Age ≥ 3 years: 18 mg/day	Age 3-5 years: 36 mg Age ≥ 6 years: 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, whichever is less	Once daily			
	Daytrana®TD patch✦	Age ≥ 3 years: 10 mg/day	Age 3-5 years: 20 mg Age ≥ 6 years: 30 mg/day	Approved for children 6 years and older: 30 mg/day	Once daily			
Dexmethylphenidate*	Focalin®	• Age 3-5 years: 2.5mg/day • Age ≥ 6 years: 2.5 mg twice daily	Age 3-5 years: 10 mg/day Age ≥ 6 years: 50 mg/day	Approved for children 6 years and older: 20 mg/day	Twice daily			
	Focalin®XR	• Age 3-5 years: 5 mg/day • Age ≥ 6 years: 5-10 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

✦ Daytrana®TD patch: Post marketing reports of acquired skin depigmentation or hypopigmentation of the skin

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®	• Age ≥ 6 years and weight ≤70 kg: 0.5 mg/kg/day • Age ≥ 6 years and weight >70 kg: 40 mg/day	Age ≥ 6 years: 1.8 mg/kg/day or 100 mg/day, whichever is less	Approved for treatment of ADHD (age 6-17 years): 1.4 mg/kg/day or 100 mg/day, whichever is less	Once or twice daily	• Baseline and ongoing: height, weight, heart rate, and blood pressure • Onset of therapeutic effect typically delayed 3 weeks	Suicidal ideation in children and adolescents being treated for ADHD	• Severe liver injury • Contraindicated to use within 14 days of an MAOI • Increased blood pressure and heart rate • Psychiatric adverse events • Priapism (rare)
Clonidine*	Catapres® (IR)	• Age ≥ 6 years and weight <45 kg: 0.05 mg/day • Age ≥ 6 years and weight >45 kg 0.1 mg/day	Age ≥ 6 years AND • 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	• Baseline and ongoing: heart rate and blood pressure • Personal and family cardiovascular history	None	• Hypotension • Bradycardia • Syncope • Sedation/Somnolence • Taper, do not discontinue abruptly **CAUTION IF USED WITH ANTIPSYCHOTICS (↓ BP)**
	Kapvay® (ER)	Age ≥ 6 years: 0.1 mg/day	Age ≥ 6 years: 0.4 mg/day	Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD (age 6-17 years): 0.4 mg/day	Once or twice daily			
Guanfacine*	Tenex® (IR)	• Age ≥ 6 years and weight <45 kg: 0.5 mg/day • Age ≥ 6 years and weight > 45 kg: 1 mg/day	Age ≥ 6 years AND • 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	• Baseline and ongoing: heart rate and blood pressure • Personal and family cardiovascular history	None	
	Intuniv® (ER)	Age ≥ 6 years: 1 mg/day	• Age 6-12 years: 4 mg/day • Age 13-17 years: 7 mg/day	Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD • Age 6-12 years: 4 mg/day • Age 13-17 years: 7 mg/day	Once daily			
Bupropion*	Wellbutrin®	Age ≥ 6 years: 3 mg/kg/day or 150 mg/day, whichever is less	Age ≥ 6 years: 6 mg/kg/day or 300 mg/day with no single dose >150 mg, whichever is less	Not approved for children and adolescents	One to three times daily	• Blood pressure and Pulse • Mental status exam and suicide assessment	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	• Lowers seizure threshold (use caution with other agents that may lower seizure threshold-e.g. antipsychotics, TCA's, excessive alcohol) • Discontinuation syndrome • Activation of mania/ hypomania • Suicidal ideation • Contraindicated for use within 14 days of an MAOI
	Wellbutrin®SR	Same as above	400 mg/day		Once or twice daily			
	Wellbutrin®XL	Same as above	450 mg/day		Once daily			
Imipramine*	Tofranil®	Age ≥ 6 years: 1 mg/kg/day or 25 mg/day, whichever is less	Age ≥ 6 years: 4 mg/kg/day or 200 mg/day, whichever is less	Approved for treatment of enuresis in children • Age 6-11 years: 2.5 mg/kg/day or 50 mg/day, whichever is less • Age ≥ 12 years: 2.5 mg/kg/day or 75 mg/day, whichever is less Approved for treatment of depression ≥ 12 years: 100 mg/day	Twice daily	• CBC • Blood pressure and Pulse • EKG • Mental status exam and suicide assessment		• Caution with cardiac disease • Cardiac conduction abnormalities • Orthostatic hypotension • Activation of mania/ hypomania • Anticholinergic and cognitive adverse effects • Lowers seizure threshold • Discontinuation syndrome • Suicidal ideation • Contraindicated for use within 14 days of an MAOI • Use caution in those with history of suicide attempts; may be cardiotoxic in overdose
Nortriptyline*	Aventyl®	Age ≥ 6 years: 0.5 mg/kg/day	Age ≥ 6 years: 2 mg/kg/day or 100 mg/day, whichever is less	Not approved for children and adolescents	Twice daily	• CBC • Blood pressure and Pulse • EKG • Mental status exam and suicide assessment		
	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®	• Age 6-11 years: 10 mg/day • Age ≥ 12 years: 20 mg/day	• Age ≥ 6 years: 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 • Obtain serum sodium if symptoms of hyponatremia occur (e.g. headaches, confusion, etc.)	Increased risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Suicidal ideation • Activation of mania/hypomania • QTc prolongation potential (citalopram, fluoxetine, possibly escitalopram) • Discontinuation syndrome • Abnormal bleeding • Contraindicated to use within 14 days of an MAOI; for fluoxetine, do not start MAOI for 5 weeks after fluoxetine discontinuation • Serotonin Syndrome • Hyponatremia risk
Escitalopram*	Lexapro®	• Age 6-11 years: 5 mg/day • Age ≥ 12 years (MDD): 10 mg/day	• Age 6-11 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®	• Age 6-11 years: 5-10 mg/day • Age ≥ 12 years: 10 mg/day	• Age ≥ 6 years: 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 • Age ≥ 12 years: 10 mg	• Children: Not recommended • Age ≥ 12 years: 40 mg	Not approved for children and adolescents				
	Paxil®CR	• Children: Not recommended • Age ≥ 12 years: 25 mg	• Children: Not recommended • Age ≥ 12 years: 50 mg					
Fluvoxamine*	Luvox®	Age ≥ 8 years: 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	Age ≥ 8 years: 100 mg/day						
Sertraline*	Zoloft®	• Age 6-12 years: 12.5-25 mg/day • Age 13-17 years: 25-50 mg/day	• Age ≥ 6 years: 200 mg/day	Approved for treatment of OCD (age 6-17 years): 200 mg/day	Once daily			
Vilazodone	Viibryd®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence			

* Generic available

\+ CR, controlled-release

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

Antidepressants, SNRIs

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	• Age 7-11 years: 150 mg/day • Age 12-17 years: 375 mg/day	Not approved for children 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 • Hepatic function testing – baseline and as clinically indicated • CBC and EKG at baseline and as clinically indicated for Clomipramine	Increased risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Suicidal ideation • Abnormal bleeding • Severe skin reactions • Discontinuation syndrome • Activation of mania/ hypomania • Hepatotoxicity • Elevated blood pressure and pulse • Serotonin Syndrome • Seizures • Hyponatremia • Contraindicated for use within 14 days of an MAOI
Duloxetine	Cymbalta®	Age 7-17 years: 30 mg/day	Age 7-17 years: 120 mg/day	Approved for treatment of Generalized Anxiety Disorder Age 7-17 years: 120 mg/day	Once or twice daily			
Desvenlafaxine	Pristiq®	• Children: Insufficient Evidence • Age 12-17 years: 50 mg/day	• Children: Insufficient Evidence • Age 12-17 years: 100 mg/day	Not approved for children and adolescents	Once daily			
Levomilnacipram	Fetzima®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence			
Clomipramine*	Anafranil®	Age 10-17 years: 25 mg/day	Age 10-17 years: 3 mg/kg/day or 200 mg/ day, whichever is less	Approved for treatment of OCD: Age 10-17 years: 3 mg/kg/day or 200 mg/ day, whichever is less	Once daily			

Antidepressants, Other Mechanisms

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
Mirtazapine*	Remeron®	Age ≥ 3 years: 7.5 mg/day	Age ≥ 3 years: 45 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 during dosage titration and as clinically indicated • Monitor weight and height • Serum cholesterol levels • CBC baseline and peri-odically	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	• Suicidal ideation • Abnormal bleeding • Weight gain • Discontinuation syndrome • Activation of mania/ hypomania • Orthostatic hypotension and syncope • Serotonin Syndrome • Hyponatremia • Contraindicated for use within 14 days of an MAOI **In addition:** Hepatotoxicity, Seizures, and Neutropenia Potential with Mirtazapine
Vortioxetine	Trintellix®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence			

* Generic Available

\+ XR, extended-release

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® Abilify Discmelt® (oral disintegratng tab) Abilify® (oral solution	Age ≥ 4 years: 2 mg/day	• Age 4-11 years: 15 mg/day • Age ≥12 years: 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 -at baseline, at 3 months, then every 6months. • CBC as clinically indicated. • Pregnancy test – as clinically indicated • Blood pressure, pulse rate, height, weight and BMI measurement – at every visit • Sexual function– inquire 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 for the first 12 months and every 6 months thereafter. • 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 3 months. . • Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision-yearly. • EKG - Baseline and as clinically indicated • **Clozapine** Monitoring Parameters: Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/µL). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). • Prescribers and pharmacies must certify the use of Clozapine at www.clozapinerems.com	Increased the risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders	• Extrapyramidal side effects • Neuroleptic Malignant Syndrome • Tardive Dyskinesia • Hyperglycemia and Diabetes Mellitus • Prolactinemia and gynecomastia (most common with risperidone and paliperidone) • Weight gain • Dyslipidemia • Orthostatic Hypotension • Leukopenia, neutropenia, and agranulocytosis • Lowers seizure threshold • Cognitive and motor impairment potential • Hyperthermia • Dysphagia • Extrapyramidal side effects • **Olanzapine** can cause a rare but serious skin reaction known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms). Presence of a fever with a rash and swollen lymph glands, or swelling to the face requires immediate medical attention.
Quetiapine*	Seroquel® Seroquel®XR (brand only)	• Age 5- 9 years: 12.5-25 mg/day • Age 10-17 years: 50 mg/day	• Age 5- 9 years: 400mg/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	IR: One to three times daily XR: Once daily			
Olanzapine*	Zyprexa® Zyprexa Zydis®	• Age 4-5 years: 1.25 mg/day • Age 6-12years: 2.5 mg/day • Age ≥ 13years: 2.5-5 mg/day	• Age 4-5 years: 12.5 mg/day • Age 6-17 years: 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® Risperdal M-Tab® (oral disintegrating tab) Risperdal® (oral solution)	• Age 4-5 years: ○ <20 kg: 0.25 mg/day ○ >20 kg: 0.5 mg/day • Age ≥6 years: 0.5 mg/day	• Age 4-11 years: 3 mg/day • Age ≥12 years: 6 mg/day	• Approved for treatment of Schizophrenia (age 13-17 years) and Bipolar Mania or Mixed Episodes (age 10-17 years): 6mg/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) Versacloz® oral suspension	• Age 8-11 years: 6.25-12.5 mg/ day • Age ≥ 12 years: 6.25-25 mg/day	• Age 8-11 years: 150-300 mg/day • Age ≥ 12 years: 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	Saphris® (sublingual tablet)	• Age ≥ 10 years: 2.5 mg twice daily	Age ≥ 10 years: 10 mg twice daily	Approved for acute treatment of Bipolar Mania and Mixed Episodes (age 10-17 years): 10 mg twice daily	Twice daily. Avoid eating or drinking for 10 minutes after sublingual administration		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: (Age ≥ 12 years): 3 mg/day	• Children: Insufficient Evidence • Adolescents (Age ≥ 12 years), Schizophrenia: ○ 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 (age 10-17 years) ○ Weight ≤ 45 kg: 80 mg/day ○ Weight > 45 kg: 160 mg/day • Tourette's Disorder: 40 mg/day	Not approved for children and adolescents	Twice daily; take with ≥500 calorie meal		None related to youth	
Lurasidone	Latuda®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence Once daily taken with >350 calorie meal		None related to youth	
Brexpiprazole	Rexulti®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence		Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies.	

* Generic available

\+ XR, extended-release

** While iloperidone alone can cause QTc prolongation, concomitant administration with a CYP2D6 inhibitor (e.g., paroxetine) or a CYP3A4 inhibitor (e.g., ketoconazole) can double QTc prolongation compared with administering iloperidone alone.

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

Antipsychotics: First Generation (Typical)

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
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): 1000 mg/day	One to six times daily	Same as Second Generation Antipsychotics	None related to youth	• Tardive Dyskinesia • Neuroleptic Malignant Syndrome • Leukopenia, neutropenia, and agranulocytosis • Drowsiness • Orthostatic hypotension • EKG changes • Extrapyramidal symptoms • Ocular changes • Hyperprolactinemia • Anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention) • Risk of prolonged QTc interval and torsades de pointes (particularly with pimozide)
Haloperidol*	Haldol®	• Age 3-12 years weighing ○ 15-40 kg: 0.025-0.05 mg/kg/day ○ ≥ 40 kg: 1 mg/day • Age > 12 : 1 mg/day	• Age 3-12 years: 0.15 mg/kg/day or 6 mg/day, whichever is less • Age >12 years ○ Acute agitation: 10 mg/dose ○ Psychosis: 15 mg/day ○ Tourette's Disorder: 15 mg/day	Approved for treatment of Psychotic Disorders, Tourette's Disorder, and severe behavioral problems (age ≥3 years): • Psychosis: 0.15 mg/kg/day • Tourette's Disorder and severe behavioral problems: 0.075 mg/kg/day • Severely disturbed children: 6 mg/day	One to three times daily		None related to youth	
Perphenazine*	Trilafon®	• Age 6-12 years: Insufficient Evidence • Age > 12 years: 4-16 mg two to four times daily	• Age 6-12 years: Insufficient Evidence • Age > 12 years: 64 mg/day	Approved for treatment of psychotic disorders (age ≥12 years): • Outpatient: 24 mg/day • Inpatient: 64 mg/day	Two to four times daily		None related to youth	
Pimozide	Orap®	Age ≥7 years: 0.05 mg/kg	• Age 7-12 years: 6 mg/day or 0.2 mg/kg/day, whichever is less • Age ≥ 12 years: 10 mg/day or 0.2 mg/kg/day, whichever is less	Approved for treatment of Tourette's Disorder (age ≥12 years): 10 mg/day or 0.2 mg/kg/day, whichever is less	Once or twice daily		None	

* 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	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Carbamazepine*	Epitol® (tab) Tegretol® (tab, oral suspension, chewable) Tegretol®XR (tab) Carbatrol® (extended release capsule) Equetro® (extended release capsule)	• Age 4-5 years: 10-20 mg/kg/day • Age 6-12 years: 10 mg/kg/day or 200 mg/day • Age ≥ 13 years: 400 mg/day	• Age 4-5 years: 35 mg/kg/day • Ages 6-12 years: 400-800 mg/day • Age ≥ 13 years: 800- 1200 mg/day	• Age 4-5 years: 35 mg/kg/day • Ages 6-12 years: 800 mg/day • Age 13-15 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	Two to four times daily Twice daily	• CBC with differential --- baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated • Electrolytes --- baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated • Hepatic function - baseline, monthly for first three months, annually and as clinically indicated. • Pregnancy Test --- baseline as appropriate, and as clinically indicated • Carbamazepine levels ---obtain 1 week after initiation and 3-4 weeks after dose adjustment, then as clinically indicated • For patients with Asian descent, genetic test for HLA- B*1502 at baseline (prior to the initiation of carbamazepine). May use results of previously completed testing. Patients testing positive for the allele should not use carbamazepine unless benefit outweighs the risk • Consider HLA-A*3101 genetic testing at baseline for those to be considered at high risk (most common in Asian, Native American, European, and Latin American descents) • Monitor for the emergence of suicidal ideation or behavior Usual therapeutic levels 4-12 mcg/ml	• Stevens-Johnson Syndrome • Aplastic Anemia/ granulocytosis	• Stevens-Johnson Syndrome • Aplastic anemia • Suicidality • Teratogenicity • Neutropenia and agranulocytosis • Hyponatremia • Induces metabolism of itself and many other drugs (strong CYP 3A4 inducer) • Decreased efficacy of oral contraceptives • Withdrawal seizures • Contraindicated to use within 14 days of an MAOI
Divalproex Sodium*	Depakote® delayed- release tablets Depakote® ER extended-release tablets Depakote® sprinkles	Age ≥6 years: 10-15 mg/kg/day	Age ≥6 years: 30-60 mg/kg/day	Age ≥6 years: 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	• CBC - with differential and platelet count - baseline then 1 to 2 weeks after each dosage increase, every 3 months for the first year of treatment, then annually and as clinically indicated • Comprehensive Metabolic Panel (hepatic function, serum creatinine, BUN and electrolytes) – baseline, every 3 months for the first year of treatment, then annually and as clinically indicated. • Pregnancy Test – baseline as appropriate, and as clinically indicated • Valproic acid level – 1-2 weeks after initiation and dosage change, then as clinically indicated. • Weight – baseline, quarterly for the first year of treatment, then annually and as clinically indicated • Monitor for the emergence of suicidal ideation or behavior • Usual therapeutic trough levels for bipolar disorder is 50- 125 mcg/ml for Valproic acid and Divalproex delayed release (Depakote®). For divalproex extended release (Depakote® ER) it is 85 – 125 mcg/ml (trough) for the treatment of acute mania. A lower therapeutic trough level may be needed with Divalproex extended release for maintenance treatment. For extended release products, a trough level is considered to be 18 to 24 hours after the last dose	• Hepatotoxicity • Teratogenicity • Pancreatitis	• Hepatotoxicity • Pancreatitis • Urea cycle disorders • Teratogenicity • Suicidal ideation • Neutropenia and leukopenia (significant increased risk with quetiapine co-administration) • Thrombocytopenia • Hyperammonemia • Multi-organ hypersensitivity reaction • Withdrawal seizures • Polycystic ovarian syndrome • Weight gain • Alopecia
Lithium*	Eskalith® Eskalith®CR Lithobid®(ER)	• Age 6-11 years: Lesser of 15-20 mg/kg/ day or 150mg twice per day • Age ≥ 12 years: Lesser of 15-20 mg/kg/day or 300 mg twice per day	Dose adjustment based upon serum level 12 hour post dose serum level: 0.6-1.2 mEq/L	Age ≥6 years: 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 12 hour post dose serum level: 1.2 mEq/L	One to four times daily	• EKG – baseline, yearly and as clinically indicated • CBC – baseline, yearly and as clinically indicated • Thyroid studies – baseline; then TSH every 6 months and as clinically indicated • Comprehensive Metabolic Panel (BUN, creatinine, glucose, calcium, and electrolytes)-baseline, 3 months, annually and as clinically indicated. Caution: BUN:serum creatinine ratio >20 may be an indication of dehydration. • UA - baseline and as clinically indicated • Pregnancy Test - as clinically indicated • Lithium Levels – one week (i.e., 5-7 days) after initiation or dosage change, 3 months after initiation, and as clinically indicated; for maintenance treatment every 6 months, and as clinically indicated • Weight – baseline, every 6 months and as clinically indicated • Usual trough therapeutic level: 0.6-1.2 meq/L (12 hour post 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

(Continued on Page 16)

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

Mood Stabilizers (continued)

Drug (generic)	Drug (brand)+	Initial Dosage	Target Dosage Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Lamotrigine*	Lamictal®	• Age 6-11 years: 2-5 mg/ day • Age ≥12 years: 25 mg/day (increase by 25 mg every 2 weeks)	Age 6-11 years • 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 Age ≥12 yearsw • 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	Age ≥6 years: 15 mg/kg/day or 500 mg/day, whichever is less	Approved for adjunctive therapy for Seizure Disorders: Age 2-12: 400 mg/ day Age >12: 500 mg/day (use > 200mg/day in adults for bipolar depression has not conferred additional efficacy) Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established	Once or twice daily	• Renal Function - baseline and as clinically indicated • Hepatic Function - baseline and as clinically indicated • Pregnancy Test - baseline and as clinically indicated • CBC – baseline and as clinically indicated • Monitor for the emergence of suicidal ideation or behavior • Monitor for rash, especially during the first two months of therapy	Serious rashes including Stevens-Johnson syndrome	• Dermatological reactions • Potential Stevens- Johnson Syndrome; risk increased with too-rapid titration • Multi-organ Hypersensitivity reactions and organ failure • Suicidal ideation • Aseptic meningitis • Concomitant use with Divalproex increases serum Lamotrigine levels significantly (increased risk of rash/SJS without lamotrigine dose adjustment) • Concomitant use with enzyme induced AEDs (Carbamazepine, Phenytoin, Phenobarbital, Primidone) reduces serum lamotrigine levels significantly (reduced lamotrigine efficacy possible without lamotrigine dose adjustment) • 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	• Age 7-12 years: 60 mg/ kg/day or 1500 mg/day • Age 13-17 years: 60 mg/ kg/day or 2100 mg/day	Approved for treatment of Seizure Disorders as mono- therapy (age ≥ 4 years), or as adjunctive therapy in (age ≥ 2 years): 60 mg/kg/day or 1800 mg/day Safety and effectiveness for treatment of Bipolar Disorder in patients younger than 18 years had not been established	Twice daily	• CBC with differential – baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated • Electrolytes – baseline and 1 to 2 weeks after each dose increase; monthly for the first 3 months, then annually, and as clinically indicated • Hepatic function - baseline and annually • Pregnancy Test – baseline as appropriate and as clinically indicated • For patients with Asian descent, genetic test for HLA- B*1502 at baseline (prior to the initiation of oxcarbazepine). May use results of previously completed testing. • Monitor for the emergence of suicidal ideation or behavior • Obtain serum sodium if symptoms of hyponatremia occur (headaches, confusion, etc.)	None	• Hyponatremia (incidence may be as high as 24% in children) • Drug-drug interaction potential • 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
+ ER and XR, extended-release; CR, controlled release
✦EIAED's - Enzyme Inducing Anti-Epileptic Drugs (e.g. Carbamazepine, Phenobarbital, Phenytoin, Primidone)

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 5-11 years: 12.5-25 mg • Age ≥12 years: 25-50 mg	• 25-37 lbs: 12.5 mg • 38-49 lbs: 19 mg • 50-99 lbs: 25 mg • ≥100 lbs: 50 mg Evidence suggests that tolerance develops to the hypnotic effects of diphenhydramine within 5-7 nights of continuous use.	Approved for treatment of insomnia (age ≥12 years): 50 mg at bedtime	Once at bedtime	None	• Drowsiness • Dizziness • Dry mouth • Nausea • Nervousness • Blurred vision • Diminished mental alertness • Paradoxical excitation • Respiratory disease • Hypersensitivity reactions • May lower seizure threshold (avoid in epilepsy)
Trazodone*	Desyrel®	• Children: Insufficient Evidence • Adolescents: 25 mg	• Children Insufficient Evidence • Adolescents: 100 mg/day	Not approved for children or adolescents as a hypnotic	Once at bedtime	Increased the risk compared to placebo of suicidal thinking and behavior (Suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Serotonin Syndrome • Contraindicated for use within 14 days of an MAOI • Suicidal ideation • Activation of mania/hypomania • Discontinuation syndrome • Abnormal bleeding • QT prolongation and risk of sudden death • Orthostatic hypotension and syncope • Abnormal bleeding • Priapism • Hyponatremia • Cognitive and motor impairment
Eszopiclone	Lunesta®	Insufficient Evidence	Insufficient Evidence	Not approved for children or adolescents	Once at bedtime	None	• Complex sleep behaviors possible • Abnormal thinking and behavior changes • Withdrawal effects • Drug abuse and dependence • Tolerance
Melatonin	No brand name	• Age 3-5 years: 0.5mg • Age ≥6 years: 1mg	• Age 3-5 years: 0.15 mg/kg or 3 mg, whichever is less • Age ≥6 years: 0.15mg/kg or 6mg, whichever is less	Regulated by FDA as a dietary supplement and not as a medication (no FDA approved indications)	Once at bedtime or alternatively, give 5-6 hrs before Dim Light Melatonin Onset (DLMO)	None	• Sedation • May adversely affect gonadal development • Should be given directly before onset of sleep is desired due to short half-life
Ramelteon	Rozerem®	Insufficient Evidence	Insufficient Evidence	Not approved for children or adolescents	Insufficient Evidence	None	• Hypersensitivity reactions • Need to evaluate for comorbid diagnoses • Abnormal thinking and behavioral changes • CNS depression • Decreased testosterone • Hyperprolactinemia
Hydroxyzine*	Vistaril®	• Age 3-5 years: 25 mg • Age ≥6 years: 50mg	• Age 3-5 years: 25 mg • Age 6-11 years: 50mg • Age 12 years and older: 100 mg	Approved for treatment of anxiety and tension: • Age <6 years: 50 mg/day in divided doses • Age = 6 years: 50-100 mg/day in divided doses Approved as a sedative when used as a premedication and following general anesthesia: 0.6 mg/kg	Once at bedtime	None	• Drowsiness • Dry mouth • Involuntary motor activity • Blurred vision, dizziness, diminished mental alertness • Paradoxical excitation associated with a small but definite risk of QT interval prolongation and torsades de pointes

* Generic Available

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

Glossary

ANC = ABSOLUTE NEUTROPHIL COUNT

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

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

Cp = Plasma concentration

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

EKG = Electrocardiogram

EEG = Electroencephalogram

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

FDA = U.S. Food and Drug Administration

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

LFTs = Liver function tests

MAOIs = Monoamine Oxidase Inhibitors

MRI = Magnetic resonance imaging

PRN = as needed

Prolactin = A hormone produced by the pituitary gland

TFTs = Thyroid Function Tests

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Disclaimer

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

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

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

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

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