Psychotropic Medication Utilization Parameters for Foster Children

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December 2010

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Introduction and General Principles

The use of psychotropic medications by children is an issue confronting parents, other caregivers, and health care professionals across the United States. Foster children, in particular, have multiple needs, including those related to emotional or psychological stress. Foster children typically have experienced abusive, neglectful, serial or chaotic care taking environments. Birth family history is often not available. These children often present with a fluidity of different symptoms over time reflective of past traumatic and reactive attachment difficulties that may mimic many overlapping psychiatric disorders. Establishment of rapport is often 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 in foster children.

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 the prescribing of psychotropic medication. Psychological testing may be particularly useful in clarifying a diagnosis and informing appropriate treatment. 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 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. The mental health assessment should be performed by an appropriately qualified mental health professional or appropriate primary care physician with experience in providing mental health care to children. The child's symptoms and functioning should be assessed across multiple domains, and the assessment should be developmentally appropriate. It is very important that information about the child's history 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. 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 unusual stress and change in environmental circumstances associated with being a foster child, counseling or psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication. Patient and caregiver education about the mental disorder, treatment options (non-pharmacological and pharmacological), treatment expectations, and potential side effects should occur before and 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 interact with children who are in distress due to an emotional or psychiatric disorder, inadequate numbers of child psychiatrists are available to meet all of the mental health needs of children. 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. 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.

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

- A DSM-IV (or current edition) 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. Whenever possible, recognized clinical rating scales (clinician, patient, or caregiver assessed, as appropriate) 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.
- 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.
- Doses should usually be started low 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.
- In depressed children and adolescents, the potential for emergent suicidality should be carefully evaluated and monitored.
- 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 is being used in a child for a primary target symptom of aggression associated with a DSM-IV 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 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 summarizing available evidence for use of psychotropic medications in this age group (Gleason 2007). 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 nonpsychopharmacological 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 infrequently used antipsychotic 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 externalizing disorders such as conduct disorder or oppositional defiant disorders – the most common situations in which antipsychotics are prescribed in children.

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 recent study over approximately 11 weeks, the average weight gain was olanzapine (8.5kg), quetiapine (6.1 kg), risperidone (5.3 kg), and aripiprazole (4.4 kg). Olanzapine and quetiapine also caused significant increases in cholesterol and triglycerides, and risperidone increased triglycerides (Correll 2009). 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.

Depression, Suicidality, and Antidepressants

In October 2003, the FDA released a public health advisory alerting health care professionals to reports of suicidality (suicidal ideation and suicide attempts) 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 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: substance abuse, conduct disorder, 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, 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. However, it should be noted that these decreases in height were only seen in the youth who were adherent with their stimulant medications. Although both advantages and disadvantages 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 (Vitello 2008; Swanson 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 (Vitello 2008). However, a recent case control study suggests that there may be an association (Gould 2009). It is thought 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 (FDA approved product labeling for Adderall and Concerta, 2008; Perrin 2008). 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. If the child has a known history of a cardiac problem, then a cardiology consult should be considered before beginning a stimulant (Perrin 2008).

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 of commonly used psychotropic medications. The preferred drug list of medications potentially prescribed for foster children is the same as for all other 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 Medication Charts beginning on page 12.

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

The following situations indicate a need for further review of a patient's case. 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 of DSM-IV diagnosis in the child's medical record

2. Five (5) or more psychotropic medications prescribed concomitantly (side effect medications are not included in this count)

3. Prescribing of:

   (a) Two (2) or more concomitant antidepressants (if an additional one is used, may be reviewed but will be allowed if reasonable for the indications.

   (b) Two (2) or more concomitant antipsychotic medications

   (c) Two (2) or more concomitant stimulant medications[1]

   (d) Three (3) or more concomitant mood stabilizer medications

   NOTE: For the purpose of this document, polypharmacy is defined as the use of two or more medications for the same indication (i.e., specific mental disorder).

   [1] 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.

   [2] When switching psychotropics, medication overlap and cross-titration may be utilized before discontinuing the first medication

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 for a given mental disorder is prescribed before utilizing psychotropic monotherapy.

6. The psychotropic medication dose exceeds usual recommended doses.

7. Psychotropic medications are prescribed for children of very young age, including children receiving the following medications with an age of:

   - Antidepressants: Less than four (4) years of age
   - Antipsychotics: Less than four (4) years of age
   - Psychostimulants: Less than three (3) 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

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Recommendations for primary care providers on when to seek referral or consultation with a child psychiatrist can be found at http://www.aacap.org/cs/root/physicians_and_allied_professionals/when_to_seek_referral_or_consultation_with_a_child_and_adolescent_psychiatrist

Stimulants (for treatment of ADHD)

Drug	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning *	Warnings and Precautions
Amphetamine Mixed Salts *Generic available* Adderall® Adderall®XR **	5 mg/day	40 mg/day 30 mg/day-XR	Adderall approved for children 3 years and older: 40 mg/day Adderall®XR approved for children 6 years and older: 30 mg/day-XR	IR: Once or twice daily XR: Once 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 growth suppression
Dextroamphetamine *Generic available* Dexedrine® Dexedrine Spansule®	5 mg/day	40 mg/day	Approved for children 6 years and older 40 mg/day	IR: Once or twice daily Spansule: Once daily		
Lisdexamfetamine Vyvanse®	30mg/day	70mg/day	Approved for children 6 years and older 70mg/day	Once daily		
Methylphenidate *Generic available* Ritalin® Ritalin®SR Ritalin®LA Metadate® Metadate®CD Methylin® Methylin®ER Concerta® Daytrana® TD	Ritalin IR: 10 mg/day Ritalin SR: 5 mg/day Ritalin LA: 20 mg/day Metadate: 10mg/day Methylin: 10mg/day Concerta: 18mg/day DaytranaTD: 10 mg/day	60 mg/day (30mg/day-Daytrana TD) (90mg/day-Concerta)	Approved for children 6 years and older Ritalin, Metadate, and Methylin: 60 mg/day Concerta: Children: 54 mg/day Adolescents: 72 mg/day Daytrana: 30 mg/day (largest patch)	Ritalin IR: One to three times daily Ritalin SR: Once daily Metadate: Twice daily Metadate CD: Once daily Methylin: Twice daily Methylin ER: Once daily Concerta: Once daily Daytrana TD: Once daily		
Dexmethylphenidate Focalin® Focalin® XR	5 mg/day	20 mg/day	Approved for children 6 years and older Focalin 20 mg/day Focalin XR 30 mg/day	IR: Twice daily XR: Once daily		

* 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; TD, transdermal.

Other ADHD Treatments

Drug	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®	Children: 0.5 mg/kg/day Adolescents: 40 mg/day	Children: 1.4 mg/kg/day Adolescents: 80-100 mg/day	Approved for treatment of ADHD (6-17 years) Maximum dosage should not exceed 1.4 mg/kg/day or 100 mg/day, whichever is less	Once or twice daily	None	Suicidal thinking in children and adolescents being treated for ADHD	• Liver injury • Serious cardiovascular events, including sudden death, particularly in those with pre-existing structural cardiac abnormalities or other serious heart problems • Increases in blood pressure and heart rate • Psychiatric adverse events
Clonidine *Generic available* Catapres® (immediate release) Kapvay® (extended release)	IR 0.05 mg/day ER 0.1 mg/day	0.4 mg/day	Immediate release not approved for children and adolescents Extended release (brand name Kapvay®) approved for treatment of ADHD in pediatric patients (6-17 years) up to 0.4 mg/day	IR: Once to four times daily ER: Once or twice daily	None	None	• Sedation • Hypotension • Do not discontinue abruptly
Guanfacine *Generic available* Tenex® (immediate release) Intuniv® (extended release)	IR 0.5 mg/day ER 0.05 mg/kg/day	4 mg/day	Immediate relase not approved for children and adolescents Extended release (brand name Intuniv™) approved for treatment of ADHD in pediatric patients (6-17 years) up to 4mg/day	IR: Once to four times per day ER: Once daily	None		
Bupropion *Generic available* Wellbutrin® Wellbutrin®SR Wellbutrin®XL	Children: 75 mg/day Adolescents: 100-150 mg/day	The lesser of:3-6 mg/kg/day OR 400 mg/day (SR) 450 mg/day (XL)	Not approved for children and adolescents	IR: Once to three times daily SR: Once to twice daily XL: Once 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 • Discontinuation syndrome • Increased risk of bleeding
Imipramine *Generic available* Tofranil®	1 mg/kg/day	4 mg/kg/day OR 300 mg/day (Adolescents)	Approved for treatment of enuresis in children 6 years and older 2.5 mg/kg/day	Twice daily	• Pulse • ECG		
Nortriptyline *Generic available* Aventyl® Pamelor® Nortrilen®	0.5 mg/kg/day	2.5 mg/kg/day OR 150 mg/day (Adolescents)	Not approved for children and adolescents	Twice daily	• Pulse • ECG		

Antidepressants, SSRIs

Drug	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 Generic available Celexa®	Children: 10-20 mg/day Adolescents: 10-20mg/day	Children: 40mg/day Adolescents: 40mg/day	Not approved for children and adolescents	Once daily	1) Pregnancy test – as clinically indicated 2) Monitor for emergence of suicidal ideation or behavior	Increased the 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 • Discontinuation syndrome • Increased risk of bleeding
Escitalopram Lexapro®	Children: 5-10 mg/day Adolescents: 5-10 mg/day	Children: 20mg/day Adolescents: 20mg/day	Not approved for children Approved for Major Depressive Disorder in adolescents (12-17 years) 20 mg/day				
Fluoxetine Generic available Prozac®	Children: 10 mg/day Adolescents: 10-20 mg/day	Children: 30-60mg/day Adolescents: 60mg/day	Approved for pediatric patients 8 to 18 years For MDD 20 mg/day For OCD 60 mg/day				
Paroxetine Generic available Paxil® Paxil CR® (extended release)	Children: Not Recommended Adolescents: 10-20mg/day	Children: Not Recommended Adolescents: 40 mg/day or 37.5 mg/day for Paxil CR®	Not approved for children and adolescents				
Fluvoxamine Generic available Luvox® Luvox CR® (extended release)	Children: 25 mg/day Adolescents: 25 mg/day	Children: 200 mg/day Adolescents: 300 mg/day	Approved for treatment of OCD in chidlren (8-11 years) and adolescents (12-17) 300 mg/day				
Sertraline Generic available Zoloft®	Children: 25mg/day Adolescents: 50 mg/day	Children: 200 mg/day Adolescents: 200 mg/day	Approved for treatment of OCD in pediatric patients (6-17 years) 200 mg/day				

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.

Antidepressants, SNRIs

Drug	Starting Dose	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Black Box Warning	Warnings and Precautions
Venlafaxine Extended Release Effexor XR®	Children: Insufficient Evidence Adolescents: Insufficient Evidence	Children: Insufficient Evidence Adolescents: Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence	1) Pregnancy test – as clinically indicated. 2) Blood pressure during dosage titration and as clinically necessary 3) Monitor for emergence of suicidal ideation or behavior	Increased the 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 • Discontinuation syndrome • Increased risk of bleeding
Duloxetine Cymbalta®	Children: Insufficient Evidence Adolescents: Insufficient Evidence	Children: Insufficient Evidence Adolescents: Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence	1) Pregnancy test – as clinically indicated 2) Blood pressure prior to initiating treatment, during dosage titration, and as clinically indicated 3) Hepatic function testing – baseline and as clinically indicated 4) Monitor for emergence of suicidal ideation or behavior		
Desevenlafaxine Pristiq®	Children: Insufficient Evidence Adolescents: Insufficient Evidence	Children: Insufficient Evidence Adolescents: Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence	1) Pregnancy test – as clinically indicated 2) Blood pressure prior to initiating treatment, during dosage titration, and as clinically indicated 3) Hepatic function testing – baseline and as clinically indicated 4) Monitor for emergence of suicidal ideation or behavior		

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	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®	Children: 2.5 mg/day Adolescents: 5 mg/day	Children: 15mg/day Adolescents: 30mg/day	Approved for Bipolar Mania or Mixed Episodes in pediatric patients (10 to 17 years) and Schizophrenia in adolescents (13-17 years) 30mg/day Irritability associated with autistic disorder (6-17 years) 15mg/day	Once daily	1) CBC as indicated by guidelines approved by the FDA in the product labeling. 2) Pregnancy test – as clinically indicated 3) Weight and BMI measurement – when a new antipsychotic is initiated, at every visit (monthly for inpatients) for 6 months after the new antipsychotic is initiated, and quarterly when the antipsychotic does is stable. 4) Fasting plasma glucose level or hemoglobin A1c – before initiating a new antipsychotic, then yearly. If a patient has significant risk factors for diabetes and for those that are gaining weight – before initiating a new antipsychotic, 4 months after starting an antipsychotic, and then yearly. 5) Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL) cholesterol, and triglycerides] – Every 2 years or more often if lipid levels are in the normal range, every 6 months if the LDL level is > 130 mg/dl 6) Sexual function inquiry – inquire yearly for evidence of galactorrhea/ gynecomastia, menstrual disturbance, libido disturbance or erectile/ejaculatory disturbances in males. If a patient is receiving an antipsychotic known to be associated with Prolactin elevation, then 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. 7) 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. 8) Tardive Dyskinesia evaluation – every 12 months. For high risk patients (including the elderly), every 6 months.. 9) Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision – yearly 10) Ocular evaluations – every 2 years in youth ‡ 11) EKG – Baseline and as clinically indicated (Asenapine, Iloperidone, Paliperidone 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 • Akathisia • Dyslipidemia
Quetiapine Seroquel®	Children: 12.5 mg/day Adolescents: 25 mg/day	Children: 300 mg/day Adolescents: 600 mg/day	Approved Bipolar Mania (10-17 years) and for Schizophrenia in adolescents (13-17 years) 600mg/day Not approved for children	Once to twice daily			
Olanzapine Zyprexa®	Children: 2.5 mg/day Adolescents: 2.5-5 mg/day	Children: 12.5 mg/day Adolescents: 30 mg/day	Approved for Bipolar Mania or Mixed Episodes and Schizophrenia in adolescents (13-17 years) 20mg/day Not approved for children	Once to twice daily		None related to youth	
Risperidone *Generic available* Risperdal®	Children: 0.25 mg/day Adolescents: 0.5 mg/day	Children: 3 mg/day Adolescents: 6 mg/day	Approved for Bipolar Mania or Mixed Episodes in children and adolescents (10-17 years) and Schizophrenia in adolescents (13-17 years) 6 mg/day Irritability associated with Autistic Disorder (5-16 years) 3 mg/day	Once to twice daily		None related to youth	
Clozapine *Generic available* Clozaril® Fazaclo®	Children: 6.25-12.5 mg/day Adolescents: 6.25-25 mg/day	Children: 150-300 mg/day Adolescents: 200-600 mg/day	Not approved for children and adolescents	Once daily		Agranulocytosis; seizures; myocarditis; other adverse cardiovascular and respiratory effects	
Asenapine (sublingual) Saphris®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence		None related to youth	• Neuroleptic Malignant Syndrome • Tardive Dyskinesia • Hyperglycemia and Diabetes Mellitus • Weight gain • Akathisia • Dyslipidemia • Prolonged QTc interval
Iloperidone Fanapt®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence		None related to youth	
Paliperidone Invega®	Insufficient Evidence	Insufficient Evidence	Not approved for children and adolescents	Insufficient Evidence		None related to youth	
Ziprasidone Geodon®	Children: 10 mg/day Adolescents: 20 mg/day	Children: Insufficient Evidence Adolescents: 160 mg/day	Not approved for children and adolescents	Twice daily (Better absorbed when taken with food)		Not approved for depression in under age 18. Increased the risk of suicidality in short-term studies in children and adolescents with major depressive disorder and other psychiatric disorders	

† Dosage recommendations in this table are based on reference # 17 (Jensen, 2010).
‡ There is no current clinical consensus regarding the need for routine ocular evaluations in children and adolescents. Data from animal studies suggest that quetiapine might be associated with increased risk of cataract development, but this has not been concluded from current evidence in human use.
§ There is no current clinical consensus regarding the need for routine monitoring of QTc interval with use of Ziprasidone in children and adolescents. For additional information regarding EKG monitoring with Ziprasidone use, please refer to reference # 4 (Blair, 2005).

Antipsychotics: First Generation (Typical)

Drug	Starting Dose	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box Warning	Warnings and Precautions
Chlorpromazine✦ *Generic available* Thorazine®	Child 0.275 mg/kg Adolescent 12.5 mg	Chidlren younger than 5 years 40 mg/day Children 5-12 years 75mg/day Adolescent 800 mg/day	Approved for treatment of severe behavioral problems in children (6 months to 12 years) Outpatient Children: 0.25mg/pound every 4-6 hours Inpatient Children: 200mg/day in older children Adolescents 800 mg/day	Two to four times daily	None related to youth	• May alter cardiac conduction • Sedation • Orthostatic hypotension • EPS • Tardive Dyskinesia • Neuroleptic Malignant Syndrome • Use caution with renal disease, seizure disorders, respiratory disease, and any acute illness in children • Weight gain
Haloperidol✦ *Generic available* Haldol®	<35 kg: 0.25-0.5mg/day ≥35 kg: 1 mg/day	<35 kg: 3-4 mg/day ≥35 kg: 10 mg/day	Approved for treatment of Psychotic Disorders, Tourette's Disorder, and severe behavioral problems in children 3 years and older Psychosis: 0.15mg/kg/day Tourette's and severe behavioral problems: 0.075mg/kg/day 6mg/day	Once to three times daily	None related to youth	• Sedation • Orthostatic Hypotension • EPS • Photosensitivity • Tardive Dyskinesia • Constipation • Dry Mouth • Tachycardia • Prolactin elevation
Perphenazine *Generic Available* Trilafon®	≥ 12 years old 12 mg/day	6-12 years: 6 mg/day Adolescents: 64 mg/day	Approved for treatment of psychotic disorders in 12 years and older 64mg/day	Three times a day	None related to youth	• EPS • Tardive Dyskinesia • Dystonia • Neuroleptic Malignant Syndrome • Orthostatic hypotension • May alter cardiac conduction • Endocrine changes • Weight gain
Pimozide Orap®	1-2 mg/day	≤ 12 years 0.2 mg/kg/d 10 mg/day	Approved for treatment of Tourette's Disorder in 12 years and older 10mg/day	Once to twice daily	None related to youth	• EPS • Tardive Dyskinesia • Dyskinesias • Dry Mouth • Constipation • Prolactin Elevation • Prolongs QTc interval

✦Chlorpromazine and Haloperidol, when prescribed for severe behavioral problems, should be reserved for children with who have failed to respond to psychotherapy or medications other than antipsychotics.

Mood Stabilizers

Drug	Initial Dosage	Target Dose or Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Baseline Monitoring	Black Box Warning	Warnings and Precautions
Carbamazepine *Generic available* Carbatrol® Tegretol® Tegretol® XR	Under 6 years: 10-20mg/kg/day 6-12 years: 100mg twice a day 12 years and older: 200mg twice a day	Under 6 years: 35mg/kg/day 6-12 years: 400-800mg/day 12 years and older: 800-1200mg/day		Approved for Seizure Disorders in all ages Maximum dosages Under 6 years: 35 mg/kg/day 6-12 years: 800mg/day 12-15 years: 1000 mg/day >15 years: 1200 mg/day	Immediate Release two to four times a day Sustained Release (XR) twice a day	• CBS • Electrolytes	Stevens-Johnson syndrome Aplastic Anemia/ Agranulocytosis	• Aplastic Anemia • Neutropenia • Hyponatremia • Induces metabolism of itself and some other drugs • Decreased efficacy of oral contraceptives • Teratogenicity • Stevens-Johnson Syndrome
Divalproex Sodium *Generic available* Depakote®	250mg/day	500mg-2000mg/day	Range: 50-120 mcg/ml Frequency: Day 7 • Weekly until stable • q6 months thereafter	Approved for Seizure Disorders in 10 years and older Maximum dose based upon serum level. Serum level: 50-100 mcg/ml or 60 mg/kg/day	Two to three times daily	• Chemistry Panel • CBC (with platelets) • LFTs • Pregnancy test	Hepatotoxicity; Teratogenicity; Pancreatitis	• Hepatotoxicity • Teratogenicity • Pancreatitis • Urea cycle disorders • Multi-organ hypersensitivity reaction • Thrombocytopenia • Withdrawal seizures • Suicidal ideation • Polycystic ovaries
Lithium *Generic available* Eskalith® Eskalith®CR Lithobid®	Children: 15-20 mg/kg/day in two to three divided doses Adolescents: 300mg three time daily (or 900mg/day)	Dose adjustment based upon serum level. Serum level: 0.4-0.6 mEq/L Note: 300mg Lithium Carbonate increases serum level by 0.2 – 0.4mEq/L	Maximum dose based upon serum level. Serum level: 0.6 – 1.2 mEq/L Frequency of blood level monitoring: • Day 7 • Weekly until stable • q3 months thereafter	Approved for manic episodes and maintenance of Bipolar Disorder in 12 years and older Maximum dose Serum level: 1.2 mEq/L	Once to three times daily	• Chemistry Panel • CBC (with platelets) • Serum Creatinine • TFTs • Pregnancy test • ECG	Toxicity above therapeutic serum levels	• Toxicity above therapeutic serum levels • Renal function impairment • Special risk patients: those with significant renal or cardiovascular disease, severe debilitation, dehydration, sodium depletion, and to patients • Polyuria • Tremor • Diarrhea • Nausea • Hypothyroid • Teratogenic
Lamotrigine *Generic Available* Lamictal®	Children: 2-5mg/day Adolescents: 25mg/day (increase by 25mg every 2 weeks)	Children: • with Valproate 1-3mg/kg/day • with Valproate and EIAED's * 1-5mg/kg/day • Monotherapy 4.5-7.5mg/kg/day • with EIAED's 5-15mg/kg/day Adolescents: • with Valproate 100-200mg/day • with Valproate and EIAED's 100-400mg/day • Monotherapy 225-375mg/day • with EIAED's 300-500mg/day		Approved for adjunctive therapy for Seizure Disorders in 2 years and older Maximum dose 500 mg/day Safety and effectiveness for treatment of Bipolar Disorder in patients below 18 years has not been established	Once to twice daily initially, then twice daily for maintenance		Serious rashes including Stevens-Johnson syndrome and asceptic meningitis	• Dermatological reactions • Potential Stevens Johnson Syndrome • Acute-multi organ failure • Withdrawal seizures • Blood dyscrasias • Hypersensitivity • Suicidal ideation

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

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

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 several days.

LFTs = Live function tests

MAOIs = Monoamine Oxidase Inhibitors

Prolactin = A hormone produced by the pituitary gland.

TFTs = Thyroid Function Tests