

Psychotropic Medication Utilization Parameters For Children in State Custody

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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. Children in state custody, in particular, have multiple needs, including those related to emotional or psychological stress. Children in state custody 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 and reactive attachment difficulties that may mimic many overlapping psychiatric disorders. Establishment of rapport is often difficult. These multiple factors serve to complicate diagnosis. Children in state custody may reside in areas of the state where mental health professionals such as child psychiatrists are not readily available. Similarly, caregivers and health providers may be faced with critical situations that require immediate decisions about the care to be delivered. For these and other reasons, a need exists for treatment guidelines and parameters regarding the appropriate use of psychotropic medications for children in state custody.

Because of the complex issues involved in the lives of children in state custody, 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. 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. Appropriate screening tools should be used for children through the *Early & Prevention Screening, Diagnosis & Treatment* (EPSDT) process or who are being treated by primary care providers. Children with complicated or refractory symptoms should be referred to a qualified mental health professional for consultation or treatment. The mental health assessment should be performed by an appropriately qualified mental health professional with experience in providing 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 clinician in a timely manner, either through an adult who is well-informed about the child or through a comprehensive medical record. Psychological testing may be indicated when: a disorder is suspected but symptoms can't be reported, underlying issues are suspected that may be difficult to identify in the course of treatment, treatment fails, educational placement is needed and treatment determination is needed for sexually inappropriate actions.

The role of nonpharmacological 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, severe impulsivity endangering the child or others, marked disturbance of psychophysiological functioning (such as profound sleep disturbance), or marked anxiety, isolation, or withdrawal, or for conditions in which research has clearly indicated the superiority of pharmacotherapy (e.g., ADHD). Given the unusual stress and change in environmental circumstances associated with being a child in state custody, counseling or psychotherapy (including behavioral therapies) should generally begin before or concurrent with prescription of a psychotropic medication. Patient and caregiver education about the mental disorder, treatment options (nonpharmacological and pharmacological), treat 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 in which it has been studied by the manufacturer. The FDA also 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 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 they feel is best for each individual patient.

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

- A DSM-IV TR 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 over all benefit-to-risk of pharmacotherapy. The clinician should also take into consideration birth control status, potential

for pregnancy, and other potentially complicating medical conditions or medications.

- Except in the case of 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 of 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 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 psychiatrist should occur if the child's clinical status has not experienced meaningful improvement within a timeframe that is appropriate for the child's clinical status and the medication regimen being used.
- When medication changes are warranted within the same class of medications, a 60 day cross-over period of titration of the new agent and taper of the agent to be discontinued is appropriate unless the agent to be discontinued is causing adverse effects.
- 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 TR 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 effect, treatment plan, and intended use of prescribed medications.

Criteria Triggering 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/adolescent 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) Four (4) or more psychotropic medications prescribed concomitantly.

Note:

- a) 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).*
- b) The prescription of side effect agents of benztropine or diphenhydramine does not count toward the total psychotropic number.*

- 3) Prescribing:

- a) Two (2) or more concomitant antidepressants,
- b) Two (2) or more concomitant antipsychotic medications,
- c) Two (2) or more concomitant stimulant medications⁽¹⁾, or
- d) Two (2) or more concomitant mood stabilizer medications.

(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.

- 4) The prescribed psychotropic medication is not consistent with the patient's diagnosis or the patient's target symptoms (i.e., specific symptoms observed in a child/adolescent that are associated with a mental disorder, and that usually respond to the medication being prescribed).

- 5) Psychotropic polypharmacy for a given mental disorder is prescribed before utilizing psychotropic monotherapy.
- 6) The psychotropic medication dose exceed usually recommended doses.⁽²⁾
- 7) Psychotropic medications are prescribed for children five (5) years and under.
- 8) Prescribing by a primary care provider for a diagnosis other than the following single DSM-IV TR Axis I diagnosis (unless recommended by a consultant in the specialties of: pediatric neurology, psychiatry, or developmental behavioral pediatrician).
 - Attention Deficit Hyperactive Disorder (ADHD)
 - Encopresis
 - Enuresis
 - Mild-moderate anxiety disorders,
 - Mild-moderate depression,
 - Mild-moderate developmental disorders
 - Mild-moderate sleep disorders
 - Mild-moderate tic disorders

(2)Usual recommended maximum doses of common psychotropic medications.

Note

- a) *These tables are intended to reflect usual maximum doses of commonly used psychotropic medications. The preferred drug formulary potentially prescribed for children in state custody is the same as for all other TennCare recipients.*
- b) *These doses represent usual daily maximum doses, and are intended to serve as a guide for clinicians. The tables are not intended to serve as 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 care monitoring and documentation of response to treatment should be observed.*
- c) *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.*

Antidepressants/Anxiolytics

	Maximum Dose per Day⁽¹⁾	
	<i>Children</i>	<i>Adolescents</i>
Citalopram	40mg	60mg
Escitalopram	20mg	20mg
Fluvoxamine ⁽²⁾	200mg	200mg
Fluoxetine ^(2, 3)	20mg	40mg

Paroxetine	30mg	40mg
Sertraline (2)	200mg	200mg
Venlafaxine	3 mg/kg/d	225mg

- (1) *In general, doses should be started low and titrated slowly while monitoring the patient for improvement in depressive symptoms, potential side effects, or emergent suicidality*
- (2) *Has FDA approved labeling for treatment of depression in children.*
- (3) *Has FDA approved labeling for treatment of anxiety disorders in children.*

Antipsychotics

	Maximum Dose per Day	
	<i>Children</i>	<i>Adolescents</i>
Aripiprazole	15mg	30mg
Clozapine	300mg	600mg
Haloperidol	10mg	20mg
Olanzapine	12.5mg	20mg
Quetiapine	300mg	600mg
Risperidone	4mg	6mg
Ziprasidone	No data	180mg

ADHD Medications

	Maximum Dose per Day	
	<i>Children</i>	<i>Adolescents</i>
Stimulants		
Amphetamine (Mixed amphetamine salts Or dextroamphetamine)	40mg	40mg
Dexmethylphenidate	20mg	20mg
Methylphenidate	60mg	72mg
Others		
Atomoxetine	1.8mg/kg/d	100mg
Bupropion	6mg/kg/d	450mg
Clonidine	0.4mg	0.4mg
Guanfacine	4mg	4mg
Imipramine	5mg/kg/d	300mg
Nortriptyline	3mg/kg/d	150mg

Mood Stabilizers

	Maximum Dose per Day	
	<i>Children</i>	<i>Adolescents</i>
Carbamazepine (3)	7mg/kg/d	(Max Cs: 12mcg/mL)
Lamotrigine	15mg/kg/d (200mg)	200mg
Lithium (3)	30mg/kg/d	(Max Cs: 1.2mEq/L)
Valproic acid (3) (Divalproex)	20mg/kg/d	(Max Cs: 125mcg/ml)

(3) Maximum daily dose typically determined by drug serum concentration (Cs) and individual patient tolerability.