Psychotropic Medication Guidelines for Youth in Care with the Indiana Department of Child Services

Approved 2/22/2018

Developed by the Indiana Psychotropic Medication Advisory Committee (PMAC), Psychotropic Advisory Subcommittee

2018 Psychotropic Advisory Subcommittee Members:
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About the Indiana Psychotropic Medication Advisory Committee (PMAC)

The Indiana Psychotropic Medication Advisory Committee (PMAC) was launched in January, 2013 to review the psychiatric treatment of DCS-involved youth, with a specific focus on psychotropic medication utilization patterns. This committee includes representatives from IUSM Department of Psychiatry, DCS, OMPP, DMHA, pediatricians, social workers, psychologists, pharmacists, child advocates and other identified stakeholders (see 2014 members below; see current, 2018 members below). The PMAC monitors Federal legislation, reviews best-practice guidelines for psychotropic medication use, monitors Indiana prescription patterns, reviews formularies and makes policy recommendations to DCS. Specific responsibilities of the committee include the following:

- Review the literature on psychotropic medication best practice (e.g., AACAP) and provide guidance to DCS, OMPP, IUSM and prescribing providers;
- Provide assistance to DCS in establishing a consultation program for youth in state care who are prescribed psychotropic medications;
- Publish guidelines for the utilization of psychotropic medications among DCS-involved youth, with revisions made on a semi-annual basis, as needed;
- Review DCS policies for requesting and obtaining consent to treat DCS-involved youth with psychotropic medications and make recommendations for change to DCS Permanency and Practice Support Division; and
- Identify non-pharmacologic, evidence-based mental health treatments for DCS-involved youth.

Founding (2014) PMAC Members:

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Appendix:
I. Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care, 5th Version, March/July 2016 (for Texas Department of Family and Protective Services)

Introduction:
In an attempt to provide improved utilization of psychotropic medications and therefore overall mental health care to Indiana’s children in the placement and care of the Department of Child Services (DCS), DCS convened a work group in 2013 to lead this effort. To guide Indiana’s prescribers, this work group, the Indiana Psychotropic Medication Advisory Committee (PMAC) agreed to adopt the September 2013 version of the *Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care* (“Texas parameters;” TP) developed by the Texas Department of Family and Protective Services and The University of Texas at Austin College of Pharmacy (for current version, see Appendix I). To consider the applicability of the Texas parameters, the PMAC tasked its Psychotropic Advisory Subcommittee with a review of the Texas parameters. As a result of this review, the Subcommittee recommended adoption of the Texas parameters with the following modifications/clarifications and additions.

In February, 2015, upon the recommendation of the Indiana Medicaid Mental Health Quality Advisory Committee (MHQAC), the Indiana Medicaid Drug Utilization Review (DUR) Board approved exempting drug therapy regimens, based upon recommendations from the IUSM Department of Psychiatry, from prior authorization (PA). Subsequently, managed care entities (MCEs) administering pharmacy benefits for affected youth agreed to participate in this program and adopted the PA exemption process.

A revision was completed January 2016. This current version was revised, incorporating updated Texas parameters (Version 5), January 2018.

I. Modifications/Clarifications:

General Principles:

1. In the state of Indiana, a comprehensive evaluation prior to the use of medications should be performed by a licensed professional or a qualified professional under the supervision of a licensed professional.
2. To clarify, a physical examination is not typically completed by a child psychiatrist or necessarily required for the use/start of psychotropic medications (excluding evaluation for extrapyramidal or other movement side effects). If warranted, it is the responsibility of the evaluating mental health professional to refer the child for a physical examination.
3. A standardized trauma assessment (e.g., CANS, Trauma Symptom Checklist) is preferred for clinical assessment of exposure of trauma and maltreatment. For youth with more extensive trauma histories, a comprehensive trauma assessment may recommended by DCS. The service standard for comprehensive trauma assessments can be found at [http://www.in.gov/dcs/3159.htm](http://www.in.gov/dcs/3159.htm).
4. In addition to the need to identify DSM-5 diagnoses to direct treatment, diagnoses outlined in the relevant version of the International Classification of Diagnoses (e.g., ICD-10) are also appropriate.

5. In addition to diagnoses, benefits/risk, lab findings, adverse events, alternatives, and risks of no treatment, informed consent should also include a discussion of possible medication interactions.

6. If a child does not improve in the care of a non-child psychiatrist, TP recommends referral to a child psychiatrist. We would like to clarify that the window for expected improvement for most childhood psychiatric disorders is 3 months.

7. When treating youth with medication for aggression, TP recommend a slow taper with discontinuation every 6 months. To clarify, youth with aggression resulting from any of the following disorders should be given an opportunity for a taper: oppositional defiant disorder, conduct disorder, disruptive mood dysregulation disorder, developmental disabilities and autism spectrum disorder. We would like to further note that such tapers may not be routine in current clinical practice, but they are now highly recommended.

**Medication-Specific Recommendations**

1. Although short acting alpha agonists for use in the treatment of ADHD and tics are not FDA approved, they remain the recommended first line agents.

2. Tapering antipsychotics in children may require longer than a 4 week period.

3. See Tables for additions

4. Routine lipid screening is recommended annually, rather than every 6 months, as outlined in the TP. If abnormal values are detected, more frequent monitoring (every 3-6 months) is recommended.

5. Fasting lipids and glucose are recommended to be checked on every pediatric patient prior to starting (or at first contact if medication has already been started) medications known to impact these labs (e.g., antipsychotics).

6. Evaluation of blood pressure, heart rate, weight and height is recommended for every medication monitoring visit and initial evaluation.

7. Clomipramine is recommended for obsessive compulsive disorder if the child or adolescent has failed two complete trials of serotonin reuptake inhibitors.

8. Due to concerns about the potential for cardiac conduction abnormalities, citalopram should not be prescribed at doses greater than 40 mg daily.

9. Orap (pimozide) should be used for the treatment of tics only if Haldol use was a failure or intolerable.

10. Aripiprazole dosage for the treatment of tics is as follows (per package instructions):

<table>
<thead>
<tr>
<th>Patient Weight</th>
<th>Start dose</th>
<th>Recommended dose</th>
<th>Maximum dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 kg</td>
<td>2 mg</td>
<td>5 mg</td>
<td>10 mg</td>
</tr>
<tr>
<td>&gt;= 50 kg</td>
<td>2 mg</td>
<td>10 mg</td>
<td>20 mg</td>
</tr>
</tbody>
</table>

**II. Additions:**
General:

1. Rating scales used to identify response to treatment can be identified in numerous sources. A large number of evidence-based assessment tools are available free of charge for provider use in the DSM-5 (www.psychiatry.org/practice/dsm/dsm5/online-assessment-measures).
2. We would like to call special attention to best practices for care of very young children, particularly those laid out in Gleason et al, 2007 (see Appendix II).
3. Given problematic weight gain among youth on psychotropic agents, diet and exercise counseling with referrals to primary care physicians, dieticians and specialized pediatricians is recommended for any child with weight changes, ideally early in the treatment course.
4. Conversely, youth on stimulants who are unable to gain weight at a rate appropriate for age should be assessed for stimulant dosage reduction or discontinuation. Dietary counseling is recommended.

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 differ from those set out in the TP and are intended to fully replace page 8 of the 2013 TP. 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 complete DSM-5 (or comparable ICD-10) diagnosis in the youth’s medical record
2. Four (4) or more psychotropic medications prescribed concomitantly
3. Any psychotropic medication prescribed to a child less than one (1) year of age
4. Prescribing of:
   • Stimulants to a child less than three (3) years of age
   • Antipsychotics to a child less than four (4) years of age
   • Antidepressants to a child less than four (4) years of age
   • Mood stabilizers to a child less than four (4) years of age
5. The psychotropic medication dose exceeds usual recommended doses (FDA and/or literature based maximum dosages).
6. The prescribed psychotropic medication is not consistent with the appropriate care for the patient’s diagnosed mental disorder or with documented target symptoms usually associated with a therapeutic response to the medication prescribed.
7. Psychotropic polypharmacy (2 or more medications) for a given mental disorder is prescribed before utilizing psychotropic monotherapy.
8. Prescribing of:
   • Two (2) or more concomitant stimulants*
Two (2) or more alpha-2 agonists, including the combination of short- and long-acting agents (i.e. clonidine ER plus clonidine immediate release)
Two (2) or more concomitant antidepressants
Two (2) or more lithium-based agents
Three (3) or more concomitant lithium-based mood stabilizers or other mood stabilizers (e.g., anticonvulsants)
Two (2) or more antipsychotics
Three (3) or more sedative-hypnotics
Two (2) or more benzodiazepines
Any long acting injectable antipsychotic
Excessive (2 weeks of 4 or more days with PRN use) or inappropriate (3 or more at once; high dose) PRN medication use

*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.

9. Use medications (in a particular age range, when specified) when no evidence exists to support their use for psychiatric indications:

Stimulants and alternatives
amphetamine aspartate/amphetamine sulfate/dextroamphetamine (< 3 yrs)
nortriptyline

Antidepressants
isocarboxazid (< 16 yrs)
phenelzine sulfate (< 13 yrs)
tranylcypromine sulfate (< 13 yrs)

Antidepressants, SSRIs
paroxetine HCl/mesylate

Antidepressants, TCAs
amitriptyline HCl (< 13 yrs)
amoxapine (< 16 yrs)
nortriptyline (< 13 yrs)

Antipsychotics, Typical
thioridazine HCl (< 2 yrs)

Barbiturates
Butisol

Benzodiazepines
chlordiazepoxide HCl (< 6 yrs)
Mood Stabilizers

- divalproex sodium (< 10 yrs)
- valproic acid (< 2 yrs)
- valproate sodium (< 2 yrs)
- lamotrigine (< 2 yrs)

III. Tables:
To address new medications or additional information, the following tables have been added, in order to supplement the tables provided in the TPs. [Abbreviations used in tables: Insufficient evidence=IE; Food and Drug Administration=FDA; NA= Not FDA approved for children or adolescents (i.e., safety and effectiveness in pediatric patients has not been established); milligram = mg]

Table 1. Long-Acting Injectable Psychotropic Medications

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dosage</th>
<th>Literature Based Maximum Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol decanoate</td>
<td>Haldol® decanoate</td>
<td>50mg¹</td>
<td>100mg³</td>
<td>NA</td>
<td>Monthly</td>
</tr>
<tr>
<td>Fluphenazine decanoate</td>
<td>--</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Risperidone long-acting injection</td>
<td>Risperdal® Consta®</td>
<td>--</td>
<td>25mg²</td>
<td>NA</td>
<td>Every 2 weeks</td>
</tr>
<tr>
<td>Paliperidone palmitate</td>
<td>Invega® Sustenna®/</td>
<td>--</td>
<td>39mg³/273mg, 410 mg, 546mg, 819mg</td>
<td>NA</td>
<td>Monthly for Sustenna Every 3 months for Trinza</td>
</tr>
<tr>
<td>Olanzapine for extended release injectable suspension</td>
<td>Zyprexa® Relprevv™</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Aripiprazole for extended release injectable suspension</td>
<td>Abilify Maintena™</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Aripiprazole lauroxil extended-release injectable suspension</td>
<td>Aristada™</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
<tr>
<td>Naltrexone for extended</td>
<td>Vivitrol®</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>IE</td>
</tr>
</tbody>
</table>
Release injectable suspension (opiate/alcohol use disorders) (see Table 5)

References:

Warnings and precautions, including black box warnings are the same as the oral preparations except for a delirium/sedation syndrome (including agitation, anxiety, confusion, disorientation) that has been observed following use of Zyprexa Relprevv.

### Table 2. Sedative-Hypnotics Agents

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dosage</th>
<th>Literature Based Max Dosage</th>
<th>FDA Approved Maximum Dosage for Children and Adolescents</th>
<th>Schedule</th>
<th>Black Box</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zolpidem</td>
<td>Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist</td>
<td>≤ 17 years: 0.25mg/kg at bedtime¹</td>
<td>0.5mg/kg OR 20mg¹</td>
<td>NA</td>
<td>Nightly</td>
<td>--</td>
</tr>
<tr>
<td>Zaleplon</td>
<td>Sonata</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

Warnings and Precautions:

**Adverse Psychiatric Events:** Abnormal thinking and behavioral changes (e.g., aggressiveness, uncharacteristic extroversion, bizarre behavior, agitation, hallucinations, depersonalization, amnesia) may occur unpredictably. Possible worsening of depression (including suicidal thinking) with sedative or hypnotic use in patients with depression. Immediately evaluate any new behavioral sign or symptom.

**Complex Sleep-related Behaviors:** Complex behaviors such as sleep-driving (i.e., driving while not fully awake after ingesting a sedative and hypnotic drug, with no memory of the event), preparing and eating food, making phone calls, or having sex while not fully awake after taking a sedative and hypnotic drug, and usually with no memory of the event, reported.

**Withdrawal Effects:** Rapid dosage reduction or abrupt discontinuance of sedatives or hypnotics has resulted in signs and symptoms of withdrawal.

**Abuse Potential:** Abuse potential similar to that of benzodiazepines and related hypnotics.
**Sensitivity Reactions**: Angioedema involving the tongue, glottis, or larynx reported rarely following initial or subsequent doses of sedative and hypnotic drugs, including zolpidem. Some patients experienced additional symptoms (e.g., dyspnea, closing of the throat, nausea and vomiting [suggestive of anaphylaxis]). Some individuals required medical treatment in an emergency department. Angioedema reported during post-marketing surveillance.

References:

**Table 3. Other Antipsychotics.**

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Trade name</th>
<th>Initial dosage</th>
<th>Maximum dosage</th>
<th>FDA max</th>
<th>Schedule</th>
<th>Black Box</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cariprazine</td>
<td>Vraylar</td>
<td>IE</td>
<td>IE</td>
<td>IE</td>
<td>NA</td>
<td>Mortality in Elderly Patients with dementia</td>
<td>same</td>
</tr>
<tr>
<td>Thioridazine</td>
<td>Mellaril</td>
<td>0.5 mg/kg/d</td>
<td>3mg/kg/d</td>
<td>800 mg</td>
<td>TID</td>
<td>QT changes Mortality in Elderly Patients with dementia Tardive Dyskinesia</td>
<td>NMS Leukopenia</td>
</tr>
<tr>
<td>Trifluperazine</td>
<td>Stelazine</td>
<td>1 mg</td>
<td>15 mg</td>
<td>Q-BID</td>
<td>same</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Loxapine</td>
<td>Loxitane</td>
<td>10 mg</td>
<td>250 mg/d</td>
<td>same</td>
<td>same</td>
<td>same</td>
<td>same</td>
</tr>
</tbody>
</table>

**Notes:**
- Trifluperazine is labeled for “Children, ages 6 to 12, who are hospitalized or under close supervision.”
- Loxapine—Very limited data on use in children; Label has no information on children. An OVID search of “loxapine & children” found only one positive case report 5 mg tid is positive in a child who had dystonia on Haldol, elevated AST on risperidone & olanzapine, no effect of quietapine by history( J Child Adolesc Psychopharm V16 2006, pp 639-634) and one letter to the editor about an 8 year old boy who overdosed on 15 ml when prescribed 0.6 ml. Dose listed above is from table on p 233 of Wolraich et al. Developmental-Behavioral Pediatrics: Evidence and Practice, 2008.
- Clinical Pharmacology: “Thioridazine has not been evaluated for use in children under the age of 2 years. Thioridazine should not be used to treat conditions in children for which specific pediatric dosages have not been established. There is no known indication for use of thioridazine in infants or neonates.”
- Older antipsychotics are no longer used commonly in children. Extrapyramidal movement disorders, QT changes and the increasing evidence base for newer “atypical antipsychotics” have much diminished their use. None are labeled for use in children. Newer textbooks frequently do not list them in in tables of treatment of children with disabilities. FDA labeling is often old without consideration of more recent standards.

**Table 4. Tricyclic Antidepressants**
<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dose</th>
<th>Lit. based max. dosage</th>
<th>FDA-Approved Max Dosage for Children and Adoles.</th>
<th>Schedule</th>
<th>Patient Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
</table>
| Amitriptyline (for depression) | Elavil | 10 mg TID | IE | 150mg daily (for 12 and above; not recommended in <12) | Three times daily | Pulse ECG | Suicidality | ●Use in combination with MAOIs  
●Suicidal ideation  
●Activation of mania/hypomania  
●Lowers seizure threshold  
●Discontinuation syndrome  
●Caution with cardiac disease |
| Clomipramine (for OCD) 10 and older | Anafranil | 25 mg daily | IE | 3 mg/kg/day or 200 mg, whichever is smaller | May give as single qHS dose once tolerated | Pulse ECG | See amitriptyline | See amitriptyline |
| Protriptyline (for depression) | Vivactil | 5 mg TID | | 60 mg daily (for 12 and above?) | Three to four times daily | Pulse ECG | See amitriptyline | See amitriptyline |
| Imipramine (in children, efficacy established for nocturnal enuresis only) | Tofranil | 30 mg daily for teens | IE | 2.5 mg/kg/day in children; doses above 100 mg daily in teens “generally not necessary” | Divided doses | Pulse ECG | See amitriptyline | See amitriptyline  
●Methylphenidate raises blood level  
●Imipramine may block clonidine effect |
| Desipramine | Norpramine | 25 mg | IE | Usual maximum 100 mg daily; up to 150 mg in more severely ill | Daily dose | Pulse ECG | See amitriptyline and imipramine | See amitriptyline and imipramine |

Table 5. Medications used to treat substance use disorders

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dose</th>
<th>Lit. based max. dosage</th>
<th>FDA-Approved Max Dosage for Children and Adoles.</th>
<th>Schedule</th>
<th>Patient Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings and Precautions</th>
</tr>
</thead>
</table>
| Naltrexone | Vivitrol (IM) Or orally dosed naltrexone (PO; revia) | 380 mg (IM) or 25 mg (PO) | IE | None (FDA approved in adults for treatment of alcohol and opioid use disorders) | Once monthly (IM) and once-twice daily (PO) | Urine drug screen (must be abstinent for 7 days) Liver functions | None | ●can precipitate severe opioid withdrawal  
●Dose related hepatotoxicity |
While no medication is FDA approved to treat substance use disorders in adolescents younger than 16, there is a pressing clinical need to judiciously use such medications, at times. A small number of case reports and clinical trials suggest that each of these medications can be efficacious when used appropriately in adolescents, while no research supports their use in children.

Table 6. New Stimulant Preparations

<table>
<thead>
<tr>
<th>Drug (generic)</th>
<th>Drug (brand)</th>
<th>Initial Dose</th>
<th>Lit. based max. dosage *</th>
<th>FDA-Approved Max Dosage for Children and Adoleses.</th>
<th>Schedule</th>
<th>Patient Monitoring</th>
<th>Black Box Warning</th>
<th>Warnings/Precautions &amp; Additional Info</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextroamphetamine sulfate</td>
<td>Zenzedi</td>
<td>Age 3-5: 2.5mg/day Age ≥6: 5mg once or twice daily</td>
<td>Age 3-5: 40mg/day Age ≥6: 40mg/day</td>
<td>Once or twice daily; 2nd dose should be administered at 4-6 hours interval</td>
<td>Same as other dextroamphetamine products</td>
<td>High potential for abuse and dependence</td>
<td>Immediate release tablets</td>
<td></td>
</tr>
</tbody>
</table>

*As these are simply new preparations of long established medications, the literature based maximum dose is specific for the product itself, and not the compound.

Table 7. Literature-based ADHD Medication Dosage by Weight
<table>
<thead>
<tr>
<th>Medication</th>
<th>Mg/kg/day</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stimulants</strong></td>
<td></td>
</tr>
<tr>
<td>Dexamfetamine</td>
<td>0.5-1.0</td>
</tr>
<tr>
<td>Dextroamphetamine</td>
<td>0.3-1.0</td>
</tr>
<tr>
<td>Mixed amphetamine salts</td>
<td>0.5-1.5</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>1.0-2.0</td>
</tr>
<tr>
<td><strong>Non-stimulants</strong></td>
<td></td>
</tr>
<tr>
<td>Atomoxetine</td>
<td>0.5-1.4</td>
</tr>
<tr>
<td>Clonidine</td>
<td>0.003-0.010</td>
</tr>
<tr>
<td>Guanfacine</td>
<td>0.015-0.05</td>
</tr>
</tbody>
</table>