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

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

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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.

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Appendix:

I. Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care, 65th Version, June 2019 (for Texas Department of Family and Protective Services)

II. Butler, M., & Curtin, M. (September 2019). “Therapy Cheat Sheet”. Indiana University School of Medicine, Indianapolis, IN.

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 first revision was completed January 2016. A second revision incorporated updated Texas parameters (Version 5), January 2018. A third revision incorporated updated Texas parameters (Version 6) completed July 2020. This current revision was completed April 2023.

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 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., Child and Adolescent Needs and Strengths (CANS), Trauma Symptom Checklist] is preferred for clinical assessment of exposure to trauma and maltreatment. For youth with more extensive trauma histories, a comprehensive trauma assessment may be recommended by DCS. The service standard for comprehensive trauma assessments can be found at http://www.in.gov/dcs/3159.htm.
4. To direct appropriate treatment with psychotropic medication, diagnoses should be based on the Diagnostic and Statistical Manual of Mental Disorders, 5th version (DSM-5).
5. Rating scales used to aid in diagnosis and identify response to treatment can be identified in numerous sources. A number of evidence-based questionnaires/rating scales can be found at the following link: https://projectteachny.org/rating-scales/
6. In addition to diagnoses, benefits/risk, lab findings, adverse events, alternatives, and risks of no treatment, informed consent to begin a psychotropic medication should also include expected duration of use and a discussion of possible medication interactions.
7. 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 child and adolescent psychiatric disorders is 3 months.
8. When treating youth with medication for aggression, TP recommends 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 comorbid ADHD and tics are not FDA approved, they remain the recommended first line agents.
2. See Tables for additions
3. 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.
4. 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).
5. Although discontinuing an atypical antipsychotic (AAP) in adolescents with metabolic abnormalities is recommended, if the AAP is deemed essential for treatment then a trial of metformin may be helpful. Metformin is FDA-approved as an adjunct to diet and exercise to treat type 2 diabetes in patients 10 years of age

and older and has evidence for reducing body-mass index in children ages 10-17 without diabetes.

6. Recommend vitamin D monitoring for any patient on an anticonvulsant. Initial levels should be drawn at 6 months and if deficient at first level, supplement and monitor every 3 months until normal. If not deficient would recommend monitoring annually.
7. Obtain a baseline and annual EKG with use of any QTc-prolonging antipsychotic and/or with using two or more QTc prolonging agents concurrently.
8. Evaluation of blood pressure, heart rate, weight and height is recommended for every medication monitoring visit and initial evaluation. For telehealth visits in which vital signs cannot be obtained in the office the prescriber should attempt to obtain this information from caregivers and/or the youth's primary care provider.
9. Clomipramine is recommended for obsessive compulsive disorder if the child or adolescent has failed two complete trials of serotonin reuptake inhibitors.
10. Due to concerns about the potential for cardiac conduction abnormalities, citalopram should not be prescribed at doses greater than 40 mg daily.
11. Orap (pimozide) should be used for the treatment of tics only in the context of a failed haloperidol trial.
12. Aripiprazole dosage for the treatment of tics is as follows (per package instructions):

Patient Weight	Start dose	Recommended dose	Maximum dose
<50 kg	2 mg	5 mg	10 mg
>/= 50 kg	2 mg	10 mg	20 mg

III. Additions:

General Principles:

1. Bipolar Disorder and Schizophrenia are extremely rare in children (<13 years old) and rare in adolescents. These diagnoses should be made strictly following DSM-5 criteria. For children and adolescents with histories of complex trauma, Autism Spectrum Disorder, developmental delays/intellectual disabilities, and/or substance use, symptoms concerning for Bipolar Disorder and Schizophrenia should be evaluated carefully within the context of these factors.
2. Evidence does not support routine clinical use of pharmacogenomic testing and pharmacogenomic guidance should not replace evidence-based medicine. Guidelines recommend selecting a medication based on current literature and FDA guidelines and only then ordering a test if the medication is included in CPIC/FDA recommendations. Clinical Pharmacogenetics Implementation Consortium (CPIC): https://cpicpgx.org/
3. Medication "washouts" (abrupt discontinuation of all psychotropic medications, either by a provider or caregiver) are not recommended.

Medication-Specific Recommendations:

1. 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 youth with weight changes, ideally early in the treatment course.

2. 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.

Psychotherapy:

In addition to ensuring that children and adolescents in the DCS system are receiving appropriate and evidenced based pharmacologic treatment for their mental health disorders, it is equally important to ensure that children who are also receiving psychotherapy interventions are receiving interventions that are also evidenced based and empirically supported. For information about specific psychotherapy approaches the Division 12 of the American Psychological Association maintains an easily accessible resource list of different treatment approaches at https://www.div12.org/psychological-treatments/treatments/ The Society of Clinical Child and Adolescent Psychology also maintains a website that provides descriptions of different evidenced based psychotherapy interventions for children and adolescents. The website also has links to videos demonstrating each of these approaches so that case managers, caregivers, and medical providers can know what to expect when a child or adolescent is participating in a certain type of psychotherapy treatment. This website can be found at: https://effectivechildtherapy.org/therapies/ . Case-managers, psychiatrists, and other medical providers can also help ensure that quality, evidenced based therapy services are being provided by asking helpful questions about therapy services during medical visits and check-ins. Examples of the types of questions that might be asked during a medical visit or check-in are included in Appendix II.

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 are the comprehensive criteria for the state of Indiana and differ from those set out in the TP on pages 9-10. 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. Multiple conflicting or redundant diagnoses
3. Four (4) or more psychotropic medications prescribed concomitantly
4. Any psychotropic medication prescribed to a child less than one (1) year of age
5. Prescribing of:
    - Stimulants to a child less than three (3) years of age
    - Antipsychotics to a child less than five (5) 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
    - Alpha Agonists to a child less than four (4) years of age

6. The psychotropic medication dose exceeds usual recommended doses (FDA and/or literature based maximum dosages).
7. 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.
8. Psychotropic polypharmacy (2 or more medications) for a given mental disorder is prescribed before utilizing psychotropic monotherapy.
9. Antipsychotic medication(s) prescribed continuously without appropriate monitoring of glucose and lipids at least annually.
10. 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, with the exception of concomitant antidepressant therapy in which one of the drugs is trazodone < 150 mg/day.
    - Two (2) or more lithium-based agents
    - Three (3) or more 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.
    Note: When switching psychotropics, medication overlaps and cross taper should occur in a timely fashion, generally within 4 weeks.

11. Use of 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
    Mydayis (≥13 yrs)
    Aptensio (≥6 yrs)

    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)
doxepin (< 18 yrs)

Antipsychotics, Typical
thioridazine HCl (< 2 yrs)

Barbiturates
Butisol

Benzodiazepines
chlordiazepoxide HCl (< 6 yrs)

Mood Stabilizers
divalproex sodium, valproic acid, and valproate sodium (< 10 yrs)
lamotrigine (< 18 yrs)
carbamazepine (< 18 yrs)
oxcarbazepine (< 18 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[4]

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule
Haloperidol decanoate	Haldol® decanoate	50mg[1]	100mg[1]	NA	Monthly
Fluphenazine decanoate	--	IE	IE	NA	IE

Risperidone long-acting injection	Risperdal® Consta®	--	25mg[2]	NA	Every 2 weeks
Paliperidone palmitate	Invega® Sustenna®/ Trinza®	--	39mg[3]/ 273mg, 410 mg, 546mg, 819mg	NA	Monthly for Sustenna Every 3 months for Trinza
Olanzapine for extended release injectable suspension	Zyprexa® Relprevv™	IE	IE	NA	IE
Aripiprazole for extended release injectable suspension	Abilify Maintena™	300mg [5]	400mg[5]	NA	Every 4 weeks
Aripiprazole lauroxil extended-release injectable suspension	Aristada™	IE	IE	NA	IE

Naltrexone for extended release injectable suspension	Vivitrol® (opiate/alcohol use disorders) (see Table 5)	IE	IE	NA	IE

References:

1. Alessi N, Alkhouri I, Fluent T, et al. Haloperidol decanoate in children. *J Am Acad Child Adolesc Psychiatry*. 2001 Aug; 40: 865-6.
2. Fu-I L, Boarati M, Stravogiannis, et al. Use of risperidone long-acting injection to support treatment adherence and mood stabilization in pediatric bipolar patients: a case series. *J Clin Psychiatry*. 2009 Apr; 70: 604-6.
3. Kowalski J, Wink L, Blakenship K. Paliperidone palmitate in a child with autistic disorder. *J Child Adolesc Psychopharmacol*. 2011 Oct; 21: 491-3
4. Lytle Sarah, McVoy Molly, and Sajatovic Martha. Long-Acting Injectable Antipsychotics in Children and Adolescents *Journal of Child and Adolescent Psychopharmacology*. February 2017, 27(1): 2-9.
5. Fortea A, Ilzarbe D, Espinosa L, et al. Long-acting injectable atypical antipsychotic use in adolescents: an observational study. J Am Acad Child Adolesc Psychiatry. 2018 Apr; 28:252-7.

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. Prescribing information for Abilify Maintena includes dosing adjustments for drug interactions mediated by cytochrome P450 2D6 and 3A4.

Table 2. Sedative-Hypnotic Agents

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Max Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Black Box
Zolpidem	Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist	≤ 17 years: 0.25mg/kg at bedtime[1,2]	0.5mg/kg OR 20mg [2]	NA	Nightly	Complex sleep behaviors[3]
Zaleplon	Sonata	IE	IE	NA	--	Complex sleep behaviors[3]

Warnings and Precautions[1]:

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-hypnotic use may occur in patients with depression. Immediately evaluate any new behavioral signs or symptoms.

Complex Sleep-related Behaviors: Complex behaviors such as sleep-driving (i.e., driving while not fully awake), preparing and eating food, making phone calls, or engaging in sexual activity while not fully awake and potentially no memory of the event, have been reported after taking sedative-hypnotics. Nonbenzodiazepine-receptor agonists, including zolpidem, are contraindicated in patients with a history of drug-induced complex sleep-related behaviors.

Withdrawal Effects: Rapid dosage reduction or abrupt discontinuance of sedative-hypnotics has resulted in signs and symptoms of withdrawal. Withdrawal from sedative-hypnotic medications can also precipitate rebound insomnia, seizures, and delirium.

Abuse Potential: Sedative-hypnotic abuse and dependance potential is similar to that of benzodiazepines and related hypnotics. Physical and psychological dependance can occur.

Sensitivity Reactions: Angioedema involving the tongue, glottis, or larynx, as well as symptoms of anaphylaxis (e.g., dyspnea, closing of the throat, nausea and vomiting [suggestive of anaphylaxis]) may occur following initial or subsequent doses of a sedative-hypnotic drug, including zolpidem. Some individuals may require medical treatment in an emergency department. Sedative-hypnotics should not be reinitiated in patients who experience angioedema after administration of the drug.

Respiratory Insufficiency: Respiratory insufficiency or oxygen desaturation may occur. Use with caution in patients with pre-existing pulmonary disease.

Next-day impairment: The risk of next-day impairment (e.g., drowsiness, prolonged reaction time, dizziness, sleepiness, blurred/double vision, reduced alertness and impaired driving) may occur for up to a full day after use.

References:

1. Zolpidem. Clinical Pharmacology database. Elsevier Inc. c2023. Accessed January 20, 2023. http://www.clinicalpharmacology.com.
2. Zolpidem. Pediatric and Neonatal Lexi-Drugs. Lexicomp Online. Wolters Kluwer Health, Inc. Accessed January 18, 2023. http://online.lexi.com
3. U.S. Food and Drug Administration. (2019, April, 30). *FDA adds Boxed Warning for risk of serious injuries caused by sleepwalking with certain prescription insomnia medicines* [Safety announcement]. https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-risk-serious-injuries-caused-sleepwalking-certain-prescription-insomnia.
4. Zaleplon. Clinical Pharmacology database. Elsevier Inc. c2023. Accessed January 20, 2023. http://www.clinicalpharmacology.com.

Table 3. Other Antipsychotics.

Generic name	Trade name	Initial dosage	Maximum dosage	FDA max	Schedule	Black Box	Warnings and Precautions
Thioridizine	Mellaril	0.5 mg/kg/d	3mg/kg/d	800 mg	TID	QT changes Mortality in Elderly Patients with dementia	Tardive Dyskinesia NMS Leukopenia
Trifluoperazine	Stelazine	1 mg	15 mg		Q-BID	same	same
Loxapine	Loxitane	10 mg	250 mg/d			same	same

Notes:

- Trifluoperazine 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 haloperidol, 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 tables of treatment of children with disabilities. FDA labeling is often old without consideration of more recent standards.

Table 4. Tricyclic Antidepressants

Drug (generic)	Drug (brand)	Initial Dose	Lit. based max. dosage	FDA-Approved Max Dosage for Children and Adoles.	Schedule	Patient Monitor-ing	Black Box Warning	Warnings and Precautions
Amitriptyline (for depression)	Elavil	10 mg TID	IE	150mg daily (for 12 and above; not recommend-ed 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 amitriptyl-ine	See amitriptyline
Protriptyline (for depression)	Vivactil	5 mg TID		60 mg daily (for 12 and above?)	Three to four times daily	Pulse ECG	See amitriptyl-ine	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 amitriptyl-ine	See amitriptyline ●Methylphenidat e raises blood level ●Imipramine may block clonidine effect
Desipramine	Norpra-mine	25 mg	IE	Usual maximum 100 mg daily; up to 150 mg in more severely ill	Daily dose	Pulse ECG	See amitriptyl-ine	See amitriptyline and imipramine

Table 5. Medications used to treat substance use disorders

Drug (generic	Drug (brand)	Initial Dose	Lit. based max. dosage	FDA-Approved Max Dosage for Children and Adoles.	Schedule	Patient Monitor-ing	Black Box Warning	Warnings and Precautions

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
Buprenorphine/naloxone	Suboxone; Subutex; Zubsolv; Bunavail	2mg/.5	IE	24mg/6mg (FDA approved for treatment of opiod use disorder in 16 and older)	Complex induction protocol; See package insert	W/drawal signs Liver functions	None	●Requires waiver from DEA to prescribe ●Risk of diversion and misuse ●Lethal in overdose
N-acetyl cysteine	none	600 mg	IE	None	Twice daily	None	None	Can cause hypersensitivity reaction, nausea, wheezing

Evidence supports the use of buprenorphine, methadone and naltrexone for maintenance treatment of opioid use disorders in adolescents. Long-acting injectable naltrexone has also been found to improve outcomes in adolescents with alcohol use disorders. N-Acetyl Cysteine (600 mg by mouth twice daily) has been shown to improve cannabis cravings and withdrawal in adolescents motivated to quit (as adjunctive treatment to psychosocial interventions).[1,2,3]

References:

1. Gray, K.M. et al. A double-blind randomized controlled trial of *N*-acetylcysteine in cannabis-dependent adolescents. Am J Psychiatry. 2012 Aug; 169(8):805-12.
2. Gray, K.M. et al. Research review: What have we learned about adolescent substance use? J Child Psychol Psychiatry. 2018 Jun;59(6):618-27.
3. Steele, D.W. et al. Interventions for substance use disorders in adolescents: A systematic review. Comparative effectiveness review no. 225. (Prepared by the Brown Evidence-based Practice Center under Contract No. 290-2015-00002-I) AHRQ publication No. 20-EHC014. Rockville, MD: Agency for Healthcare Research and Quality. May 2020. DOI: https://doi.org/10.23970/AHRQEPCCER225.

Table 6. New ADHD Medications/Preparations*

Drug (generic)	Drug (brand)	Initial Dose	Lit. based max. dosage *	FDA-Approved Max Dosage for Children and Adoles.	Schedule	Patient Monitor-ing	Black Box Warning	Warnings/Precautions & Additional Info
Viloxazine (non-stimulant)	Qelbree	Age 6 – 11: 100 mg Age 12 – 17: 200 mg		400 mg/day	Once daily	Blood pressure, heart rate, renal function	Increased risk of suicidal thoughts and behaviors	Increased heart rate and blood pressure, activation of mania/hypomania, somnolence/ fatigue Capsules may be swallowed whole or opened and contents sprinkled on applesauce or pudding

Methylphenidate	Relexxii	18 mg		Age 6 – 12: 54 mg Age 13 – 17: 72 mg (not to exceed 2 mg/kg/day)	Once daily in the morning	Usual methylphenidate monitoring	Drug dependence: use cautiously in patients with a history of substance use	Usual methylphenidate warnings and precautions; must be swallowed whole with the aid of liquids; must not be chewed, divided, or crushed
Dextroamphetamine	Xelstrym (patch)	Age 6 – 17: 4.5 mg/9 hours		Age 6 – 17: 18 mg/9 hours	Apply in the morning 2 hours before needed effect, remove within 9 hours of application	Usual dextroamphetamine monitoring	Abuse and dependence: assess risk of abuse prior to prescribing and monitor for signs of abuse and dependence	Usual dextroamphetamine warnings and precautions; specific application and disposal instructions
Serdexmethylphenidate/ dexmethylphenidate	Azstarys	Age 6 – 17: 39.2 mg/7.8 mg		52.3 mg/10.4 mg	Once daily in the morning	Usual methylphenidate monitoring	Abuse and dependence: assess risk of abuse prior to prescribing and monitor for signs of abuse and dependence	Usual methylphenidate warnings and precautions May be given with or without food; capsules may be swallowed whole or opened and contents sprinkled into 50 mL of water or over 2 tablespoons of applesauce; consume within 10 minutes of mixing

*Since prior revision July 2020
With the exception of viloxazine, the new preparations in this table are long-established medications; the literature based maximum dose is specific for the product itself and not the compound.

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