California Guidelines for the Use of Psychotropic Medication with Children and Youth in Foster Care 2018 Edition

Introduction:

Children have the right to safety, respect, justice, education, health and well-being. As a society we have the obligation to protect these values for all of our children. When children and youth have been removed from their primary homes due to abuse and/or neglect, the State of California and its counties assume the primary responsibility to safeguard these rights for the children in their care. The state also assumes the responsibility of addressing the trauma (defined below) as experienced by the child who is removed from the home and placed into care.

The California Department of Health Care Services (DHCS) and Department of Social Services (CDSS) have the shared responsibility for the oversight of mental health services provided to foster children and youth involved with county child welfare and probation agencies. The *California Guidelines for the Use of Psychotropic Medication with Children and Youth in Foster Care* is specific to those children and youth who are: (a) involved with child welfare services and/or probation services, and (b) are placed in foster care. Foster care is defined as 24-hour substitute care for children placed away from their parents or guardians and for whom the county agency has placement and care responsibility. This includes, but is not limited to, placements in foster family homes, foster homes of relatives or non-related extended family members (NREFMs), resource family homes, short-term residential therapeutic programs, group homes, emergency shelters, residential facilities, child care institutions, and pre-adoptive homes. Consistent with research over the past twenty years that has described the effects of abuse and neglect (Brown et al 1990)[1], (Lansford 2002)[2] the State is committed to utilizing formal and informal mental health services to ameliorate the negative effects of abuse and/or neglect and the potential negative effects and consequences following removal from the primary home. Together, these negative effects and potential consequences are defined as *trauma*, as defined by the Substance Abuse and Mental Health Services Administration (SAMHSA 2014) [3] as "The Three E's": The Event, The Experience, and The Effect:

> *"Individual trauma results from an event, series of events, or set of circumstances that is experienced by an individual as physically or emotionally harmful or threatening and that has lasting adverse effects on the individual's functioning and physical, social, emotional, or spiritual well-being."*

Additionally, the State recognizes that the potential for trauma can be mitigated via child and youth *resilience:* protective factors that reduce poor outcomes under conditions of adversity and risk (Greenberg, 2006)[4]. Resilience is comprised of three interactive influences: *(a)* individual differences in temperament and cognitive abilities; (b) quality of social relationships (e.g., the relationship with the primary caregiver or another supportive other); and (c) quality of the broader environment, such as school and neighborhood (Greenberg, 2006) Understanding that social relationships and the social environment can promote resilience means that the provision of informal services and access to resources that are resilience-building mitigate the effects of potential trauma (i.e., they are trauma-informed interventions) and promote optimal psychosocial functioning. Thus, the State and counties provide these resilience-building environments and activities as part of a broader array of informal mental health services for children and youth placed in out of home care. *Informal mental health services* are activities deliberately introduced to provide the child or youth opportunities for learning self-discipline, appropriate peer interactions, tolerance for frustration, enhanced self-esteem (self-affirmation), and mastery (learned control). These activities include coached team sports such as basketball, football, soccer, and baseball; art, gardening, dance, and caring for animals. Special attention should be paid to opportunities for children and youth to participate in formal training in singing (choirs, vocal groups,) and learning to play a musical instrument because data suggest these particular activities may enhance executive functioning (Kraus 2009)[5]. Additionally, coaches and teachers involved in these activities are potential sources of social support and mentoring in the child's natural environment. Thus, they are potential members of the child or youth's support network or Child and Family Team (as indicated).

Children and youth with emotional, cognitive, and/or behavioral dysregulation secondary to abuse and/or neglect are vulnerable to developing emotional patterns and behaviors that meet criteria for mental disorders as per the current *Diagnostic and Statistical Manual* (DSM –V)[6] published by the American Psychiatric Association (APA 2014) or with mental and behavioral disorders as per the current International Classification of Diseases (ICD) published by the World Health Organization[7]. These California State Guidelines reflect the understanding that these diagnostic criteria are not always consistent with current research related to the psychosocial presentations of, and best practices related to, children and youth for whom these Guidelines were developed. For this reason, these Guidelines do not always reference specific diagnoses when making treatment recommendations.

Children and youth with emotional, cognitive, and/or behavioral dysregulation have the same right to treatment as children and youth with any other health care need. Respect for the dignity of the child and the family is a prerequisite for treatment. Recognition that the child or youth with emotional, cognitive, or behavioral dysregulation may encounter social stigma and/or sub-optimal treatment is a historical concern of importance to the CDSS and DHCS. One goal of these *Guidelines* is to increase the visibility of the

strengths and needs of these children and youth to promote careful and respectful attention to individualized, optimal care. Educational efforts directed toward child welfare social workers, probation officers, family members, caregivers, attorneys, court appointed special advocates (CASAs), and health providers also are designed to address and eliminate social stigma while promoting best practices in the provision of formal and informal mental health services.

The *California Guidelines for the Use of Psychotropic Medication with Children and Youth in Foster Care,* jointly released by the CDSS and DHCS, is a statement of best practice for the treatment of children and youth in out of home care. These children and youth may require psychotropic medications. Depending on the nature, severity and persistence of their symptoms, medication may be indicated as part of an initial treatment plan (as with ADHD, major depression, psychosis and disabling anxiety); may be considered only after appropriate psychosocial interventions are employed (as with moderate anxiety/depression); or may not be indicated at all (as with learned defiance and "predatory" aggression)[8]. When psychotropic medication is indicated, it should be used in conjunction with psychosocial interventions. The exception is when psychosocial interventions have been effective and are therefore terminated but continued use of medication is necessary to prevent the recurrence of symptoms.

These *Guidelines* outline:

- Basic principles and values;
- Expectations regarding the development and monitoring of treatment plans; Principles for emotional and behavioral health care, psychosocial services, and non-pharmacological treatments;
- Principles for informed consent to medications; and
- Principles governing medication safety.

These *Guidelines* are to be used in conjunction with California State regulations related to the provision of Medi-Cal funded mental health services and community care licensing (CCL) regulations, licensing standards, and written directives related to foster homes, resource family homes, group homes, short-term residential therapeutic programs, and residential treatment centers (CA Code of Regulations 2016, Short-Term Residential Therapeutic Programs Interim Licensing Standards 2017, RFA Written Directives 2017)[9]. These Guidelines are intended to be consistent with, and promote, the values and goals of other State initiatives including the Core Practice Manual CDHCS/CDDS (2014)[10] adopted in response to the Katie A. lawsuit (CA Gov 2014)[11], the Medi-Cal Performance Outcomes System CA DHCS 2013)[12], and the Continuum of Care Reform initiative (CDSS 2014)[13].

These *Guidelines* represent the first comprehensive effort at the State level to address the use of psychotropic medication children and youth in out of home care being served by the child welfare and/or probation system. It is expected that the *Guidelines* will evolve over time in response to updated research and the evolution of best practices, and in response to feedback from youth, families, prescribers, other providers, and additional community stakeholders. For these reasons, these guidelines will be reviewed annually. In developing these G*uidelines*, the CDSS and DHCS reviewed the work of the American Academy of Child and Adolescent Psychiatry (AACAP 2008)[14], the American Academy of Pediatrics (AAP 2008)[15], California county child welfare and behavioral health policies and practices[16], and the policies of child welfare and mental health agencies in other states[17] (NJ office of Child Health Policy 2011, MMDLN & Rutgers 2010. Crystal, Ofson, Huange et al 2009.[18]. The work products of these organizations have been incorporated throughout this document. The CDSS and DHCS acknowledge the efforts of these organizations.

Basic Principles

These *Guidelines* are grounded in the following principles and values:

- Safety[19]: Child safety and health are paramount in our work, and children are, first and foremost, protected from abuse and neglect.

- Permanency: Children do best when they have strong families, preferably their own. When that is not possible, a stable, long-term placement with a relative, non-related extended family member, tribal family, foster family, or adoptive family who can meet their physical, emotional, and therapeutic needs is preferred.

- Well-Being: The State and its counties are committed to offering relevant services to children and families to meet their identified needs, build on their strengths, and promote children's development, education, physical and mental health, and general well-being.

    - Most families have the capacity to change with the support of individualized service responses.

    - Children should be placed in the least restrictive setting at which they can be safely treated. Whenever possible, this setting should be within their own community.

- Government cannot do the job alone: Real partnerships with people and agencies involved in a child's life–for example, families, tribes, medical providers, teachers, child care providers, community partners and mentors, including informal and formal mentors, community spiritual and clergy –are essential to ensure child safety, permanency, and well-being, and to build strong families.

- Child centered care: Care should be provided in a manner sensitive to the child's strengths and needs. When developmentally appropriate, children and adolescents should be a part of their health care planning, as described in the Core Practice Model developed in response to the Katie A. lawsuit.

- Continuity of care for children and youth is important: Consistent with the Core Practice Model, these *Guidelines* strive to strengthen coordination across systems of care to minimize the number of unnecessary transitions for children and youth and to support transitions that are necessary when coming into care, during care, and transitioning to permanency.

    - These *Guidelines* are consistent with, and support the goals of, Continuum of Care Reform: The treatment needs of children and youth are best met when services are provided at the lowest level of care at which the client can be safely treated.

    - Critical to the success of these Guidelines and inter-related State initiatives is access to providers who have the capacity and specialized competencies to serve our children and youth, as well as access to these providers within timeframes that meet the needs of children and youth.

- Quality: The State and its counties expect our children to receive high quality healthcare, inclusive of physical, emotional/behavioral, and dental health.

- Integration: These inclusive health care needs of a child/youth are expected to be integrated into a health care services plan that provides integrated, coordinated services that are individualized and tailored to the strengths and needs of each child and their family.

- Collaboration: The State and its counties recognize the importance of collaboration with treatment providers, particularly prescribing providers, to ensure the success of these *Guidelines* and psychotropic medication management reform for children and youth in out of home care served by child welfare and/or probation.

- Limitations: Psychotropic medication is never the sole intervention but should be part of an overall treatment strategy (T-May 2010)[20]. Medication also carries the risk of adverse (side) effects, so careful monitoring by the prescriber is essential.

CFT Treatment Plan or Comparable Mental Health Treatment Plan

Children who have emotional, cognitive, and/or behavioral dysregulation require a variety of interventions to alleviate their symptoms and to promote optimal psychosocial functioning and development[21]. If the child or youth meets Katie A. class or sub-class criteria, then the Treatment Plan[22] is a product of the Child and Family Team (Katie A Manual)[23]. The CFT is a required component of the Core Practice Model developed in response to the Katie A. lawsuit.

Additionally, one of the fundamental principles of the Continuum of Care Reform initiative is that child welfare services are most effective and "best provided in a framework that integrates service planning and delivery among multiple service systems, including the mental health system, using a team-based approach, such as a child and family team" (Welfare & Institutions Code Section 16501(a)(3)). Counties are required to convene a CFT for all children and youth residing in a group home with an existing case plan or children and youth who come into foster care after January 1, 2017, in order to identify supports and services that are needed to achieve permanency, enable a child to live in the least restrictive family setting, and promote normal childhood experiences (Welfare & Institutions Code Section 16501.1(c) and (d), CDSS All County Letter No. 16-84/DHCS MHSUDS Information Notice 16-049).

The CFT ensures that the child and family voices always are included in treatment and placement decisions. Whether or not a CFT is a required element of the child or youth's case plan, development of any Treatment Plan should include the child and family unless their participation is contra-indicated due to age, developmental status, or protective issues in the case. Treatment Plan elements include identified socio-emotional and behavioral concerns, immediate and longer term treatment goals, and interventions that are realistic for the child and family. It represents an agreement to work together toward a mutually agreed upon set of goals. CFT Treatment Plans should be reviewed and re-assessed by the treatment team, child, family, and supportive collaterals (as described below) as needed or as indicated by Katie A. status. Other Treatment Plans which may be developed by the mental health provider should also be reviewed and re-assessed by the child, family, and supportive collaterals but may not occur as part of a team meeting. All Treatment Plans require regular reviews to ensure they remain current and appropriate based on the child and family's progress in services.

The child or youth who is the focus of treatment is expected to be an active partner in the treatment planning process as developmentally appropriate. The unique abilities, strengths, and needs of the child and the family are considered in developing a plan that will work. Consideration also must be given to the range of settings within which the child is involved–home, school, work, sports and clubs–to ensure that all potential

supports and interventions are maximized to create a treatment plan that is individualized, flexible, and robust.

Treatment Plans are guided by the principle that interventions should be strength-based, child focused, and family centered. The interventions that are selected are chosen based on the child's emotional, cognitive, and/or behavioral dysregulation, the strengths and needs of the child and family, and the resources of the community.

Treatment Plans include appropriate treatments and interventions to address root causes contributing to the child's emotional, cognitive, and/or behavioral dysregulation, as well as how (and by whom) symptoms and psychosocial functioning will be monitored to evaluate treatment and intervention effectiveness. If psychotropic medication is prescribed, medication effectiveness and side-effects should be closely monitored according to the monitoring guidelines provided in these *Guidelines* (LAC DMH)[24]. It is expected that there will be ongoing communication between the prescriber and the child, parents, child's caregiver, therapists, social worker, pediatrician, public health nurse, probation officer, care coordinator, school staff, case manager, CASA, attorney, and other members of the child and family's support network, as indicated. This network constitutes the Child and Family Team, if the Team is a required component for the child or youth.

Prior to prescribing, a thoughtful benefit/risk analysis [25]is necessary, comparing the risks and expected benefits of an overall treatment plan that does *not* include medication with the risks and expected benefits of a treatment plan that does include medication (AACAP 2009, AACAP 2001)[26]. Among other considerations, one must consider the likely benefit of psychosocial interventions and of medication, the risk of adverse (side) effects from medication[27][28][29] and the risk of continued symptoms impacting the youth's psychosocial development and placement if medication is withheld.

Judicial approval (JV220, 2018)[30] is mandated by California law (California Rules of Court 5.640, 2018)[31] prior to the administration of psychotropic medications to children and youth in foster care. The Psychotropic Medication Protocol, also referred to as the JV220 process, initiates the court authorization of psychotropic medications for dependents of the court and wards of the court who are removed from the parent/guardian and placed into foster care. The JV220 documentation specifies the dosage and medication plan, ideally including targeted goals. The JV220 documentation also describes the child's diagnoses, symptoms, relevant medical history, and therapeutic services other than medication which are recommended or being provided to the child. Treatment plans may be provided to the court with the JV220 documentation when available. This is undertaken, to the extent possible, in collaboration with the child, family, caregiver, and other supportive collaterals. The prescriber should discuss the JV220 with the child, family, and caregiver, as

appropriate. Additional supportive collaterals also are included in this discussion if requested by the child or family or as indicated by State requirement (e.g., Child and Family Teams for Katie A. class and sub-class members).

Psychotropic medications should not be used for the purpose of discipline or chemical restraint, except as acutely necessary in true psychiatric emergencies (Cal. Code Regs. Tit.22 51056)[32]. Youth are not to be coerced into taking medication as a condition of placement. More information about the use of psychotropic medication in group homes and other foster care settings (such as foster family agencies, certified family homes, resource families and licensed foster family homes) is available via the CDSS Community Care Licensing Division Technical Support Program Resource Guides:

- Medications Guide for Group Homes
- Medications Guide for Foster Families

Components of a Treatment Plan

The development, implementation, and execution of a Treatment Plan includes, but is not limited to, the following individuals: the child; the child's parents (when appropriate), the child's caregiver, the prescriber, care coordinator, therapist, school staff, CWS social worker, pediatrician, attorney, public health nurse, probation officer, case manager, CASA, and other members of the child's support network or CFT (as indicated).

A best practice (Malone Localio, Huang et al 2012, Radley Finkelstein & Stafford 2006)[33], treatment plan includes the following:

- The child's diagnosis (if indicated) and a conceptualization of the child's emotional, cognitive, and/or behavioral dysregulation based on the child's history of abuse, neglect, and/or removal from the home.
- The child's baseline strengths and needs.
- Target symptoms: stated in practical and everyday language as agreed to by the child, family, and their support network or CFT.
- Client-driven short and long term treatment goals: stated in ways that can be observed and measured on a regular basis by specified means.
- Treatment interventions: evidence-supported treatments; additional psychosocial interventions such as substance abuse prevention or treatment, case management, informal mental health services, educational or behavioral

services, and/or extra-curricular and recreational activities. All identified treatments and interventions should have start dates. Psychotropic medications (if part of the Treatment Plan) also should include a re-assessment date. If medications are utilized, the dosage and medication monitoring schedule must be specified.

- Treatment and intervention periodic review and reassessment: formal treatments, e.g. (HHS 1996) evidence-supported psychotherapeutic treatments as well as psychotropic medications, are periodically reviewed by the child, family, and additional supportive collaterals (e.g., the Child and Family Team) as indicated, and in accordance with HIPAA (HHS 1996)[34]

Psychotropic Medication

For the purposes of this document, "psychotropic medication" is defined[35], per Welfare & Institutions Code 369.5(d) and 739.5(d), as "those medications prescribed to affect the central nervous system to treat psychiatric disorders or illnesses. They may include, but are not limited to, anxiolytic agents, antidepressants, mood stabilizers, antipsychotic medications, anti-Parkinson agents, hypnotics, medications for dementia, and psychostimulants."

Psychotropic medication should only be prescribed to the children and youth in a county's care as part of a comprehensive Treatment Plan, except under emergent conditions or as described above in this *Plan.* Such a comprehensive Treatment Plan includes evidence-based or best practice non-pharmacological interventions that are linguistically, culturally, and developmentally appropriate for the child or youth's needs and symptoms. Psychotropic medication prescribed to children and youth in foster care must be authorized by the court as required by Welfare & Institutions Code 369.5 and 739.5.

Authorized Prescribers of Psychotropic Medication[36]: Because of the complex medical and psychiatric needs of children in out of home placements (which include foster, kinship, NREFM care; group homes; and the juvenile justice systems), it is recommended that psychotropic medications for children be prescribed by board certified or board eligible specialists in one of the following areas of expertise:

- Psychiatry (specialization in child and adolescent psychiatry recommended)
- Neuro-developmental pediatrics
- Developmental-Behavioral pediatrics
- Pediatric neurology

- Pediatrics or family practice with specialized training in children who are at high risk or who had in utero exposure to illicit drugs or alcohol

However, if a California dependent is placed out of state, the prescriber must meet credentialing criteria for the state in which they are licensed.

Psychiatric Evaluation and Diagnosis

Evaluation Components: The psychiatric evaluation includes a thorough mental status exam, complete review of current emotional and behavioral symptoms, and the assessment for potential psychosocial precipitants for the current presentation[37]. It also should include the review of collateral documents[38] provided by CWS, when available, as described below. These records provide critical history and context for appropriate case formulation. A physical examination also is conducted or a recent physical examination is documented, as indicated. Consultation with other professionals who are treating the child, including therapists, primary care physicians, or medical specialists, is an important component to complete this information.

- **Review of Collateral Documents:** The prescriber's access to available historical information is critical for the provision of optimal care. The following documents represent optimal psychosocial history to share with the prescriber when available. Prior to the child's appointment, the prescriber is expected to review the collateral documentation when provided by the CWS social worker or probation officer. Please note that the CWS social worker or probation officer may need to obtain court authorization in order to provide copies of reports or documents from the confidential juvenile case files, or other releases of information to disclose confidential information regarding a family (such as information about a parent's substance abuse history and treatment progress).

  When the CWS social worker or probation officer is legally authorized to share copies of reports and other documentation from the case file, these reports should ideally be received at least 5 business days prior to the appointment to allow ample time for review. These documents should include:

  - Relevant sections of the Detention Hearing Report which describe what happened to the child and why the child was removed from the home. These conditions typically are the 'root cause' of the child or youth's emotional, cognitive, and/or behavioral dysregulation.

  - Relevant sections of the Jurisdiction/Disposition Report which include additional information regarding the abuse and/or neglect experienced by the child in the current referral, history of prior referrals and cases (if applicable) which provides context for the current case, and provides more details regarding why out of home care was necessary.

- Copies of significant sections of additional court reports, i.e., those that document major changes in the child or family's situation.
- Copies of all prior psychological evaluations and Initial Treatment Plans/Updates for the client.
- All prior mental health, physical health, and developmental records.
- Copies of psychiatrist's Admission and Discharge summaries and the medical H & P (History and Physical) report from all psychiatric hospitalizations for the client.
- Order Authorizing Health Assessments, Routine Health Care, And Release Of Information (Blanket Court Order) or case-specific forms signed by the Court, as per county process).
- History of Child Placement report.
- Current Health and Education Passport (HEP).
- Individualized Education Plan (IEP) and IEP Triennial evaluation (Psychoeducational Assessment Report conducted by school staff once every three years as a condition of initiating and continuing an IEP), if applicable.
- Medication log to be attached to JV 220, if available.

- **Physical Examination:** As part of the decision to initiate a medication trial, the results of the most recent physical examination, conducted within the past year, are reviewed. If no documentation is available or an examination was not completed, a brief physical examination is indicated. Including at minimum, weight, body mass index, and vital signs. When indicated by history, physical examination or psychiatric evaluation, the child may require medical specialty consultation and testing. Cardiac, endocrinological, neurological or other consultations might be indicated.
  - Baseline laboratory assessment may be advisable both to rule out medical conditions which may be contributing to or causing the symptoms, and is indicated to establish a baseline for monitoring possible medication side-effects. Refer to tables in appendix B.
  - Consider a pregnancy test, depending on case-specific circumstances, before initiating medication for a female of child-bearing age.

  - Consider a baseline screen for other substance use by the child and youth as indicated. Review of records from child welfare or probation services also can alert the prescriber to the need for substance use screening. The prescriber also may conduct a verbal screen and discuss substance use history with the child/youth.

- **Mental Status Examination:** The mental status evaluation of a child must be sensitive to the age, developmental stage, and current status of the individual child. Case conceptualization and appropriate trauma-informed diagnosis often requires multiple sessions to gain the trust of the child and to allow for a clear picture of the youngster's mental status. When indicated, the child is interviewed both with and without parents or caregivers present.

- **Diagnosis:** In developing a case conceptualization/formulation and trauma-informed diagnosis[39], the prescriber considers the child's complete presentation (strengths and challenges), developmental history, medical history, family history, past history of abuse, neglect, and/or removals, current functioning in all settings, and current mental status. If the prescriber's diagnosis is inconsistent with the diagnosis of other current treating professionals (i.e. therapists), the prescriber will discuss and reconcile these diagnostic issues with the other treating professionals to ensure that all members of the treatment team are working from the same diagnoses and case conceptualization/formulation. The diagnosis is supported by sufficient documentation to ensure that other likely potential diagnoses have been ruled out[40]. Additionally, the psychiatric evaluation addresses why the child's presentation no longer meets diagnostic criteria for prior diagnoses of record, if applicable.

- **Goals and Target Symptoms:** Specific symptoms to be targeted by the medication, based on the child's presentation and the case conceptualization/formulation, are identified. These should be documented and shared with the child, family, caregiver, and the child and family's support network (e.g., the Child and Family Team, as indicated). The prescriber documents in the record why that particular medication is the most appropriate medication at that time; estimates how soon the child, family, and other members of their support network should observe improved emotional and cognitive regulation and other signs of medication effectiveness; and estimated length of time the child will be maintained on the medication[41].

  - The targeted symptoms often are the behavioral manifestations of the child's emotional and/or cognitive dysregulation. Caution is urged to refrain from focusing on these behavioral manifestations as the sole focus of treatment, rather than treating the underlying emotional distress as the primary target of treatment.

- Regular assessment and re-assessment of medication effectiveness and side effects is expected. This is conducted via child/youth self-report in interview, collateral (e.g., teacher, coach, caregiver, social worker) reports, and (ideally) by completion of validated brief symptom screening instruments. Re-assessment also is expected to include review of meaningful measures of psychosocial functioning (e.g., improved grades, improved peer relationships at school) in the child/youth's natural environment.

- **Choice of medication:** The prescriber considers the underlying dysregulation and/or additional mental health concerns in addition to the more obvious behavioral manifestations of the child's presentation when considering the most appropriate psychotropic medication for the child at that particular time. 'Root cause' issues, as described in the Detention and Jurisdiction/Disposition Court reports as the basis for removal from the home, and possible subsequent adverse events experienced after coming into the dependency and/or delinquency systems, are critical considerations when conceptualizing targets of treatment. Thus, medication decisions are driven by case conceptualization, diagnosis, potential target symptoms, research, likely effectiveness, potential side effects, the youth's medication history, insurance formularies and available forms of medication (liquid, long-acting formulations, etc.) When there is more than one clinically sound option, the prescriber should explain the pros and cons to the youth and family and they should make the decision together. Medication is prescribed as part of a comprehensive treatment strategy that includes other non-pharmacological interventions, and is not prescribed in lieu of instituting non-pharmacological treatments that the individual child needs.

- **Informed Consent and Assent:** Respect for the independence and autonomy of the child and family is implicit in the requirement for informed consent and assent. Children are included in the consent and assent process to the extent feasible and appropriate based on their developmental stage. This means that the prescriber informs the child, family, and caregiver of the risks and benefits of the proposed treatment and the risks and benefits of alternative treatments, including absence of treatment. The prescriber explains the proposed treatment in terms that are understandable and adequate for that child, family, and additional support persons (as indicated) so that they are able to make an informed choice about whether to consent or assent to medication. This includes information about the anticipated benefits of the medication, possible risks and side effects, the range of doses, initial effects to anticipate, and what would constitute a reasonable trial. This information also should be supplied in written form when available and in the primary language of the family. Information about serious adverse effects to watch for and when and how to contact the prescriber is discussed and provided in written form. Children,

families, and caregivers should be provided ample time for questions and discussion before consent and assent are requested.

- The prescriber is expected to provide a telephone number at which the child, family, and/or caregiver can reach the prescriber or prescriber's designee if they have questions or concerns about the medications. The prescriber or designee is expected to return telephone calls within twenty-four (24) hours.

- The prescriber obtains appropriate consent to treat and authorization for the release of records by consulting with the referring child welfare social worker or probation officer to determine who can provide legal consent to treat (the biological parent or the Court in accordance with WIC 369.5 and 739.5) and who holds the privilege for authorizing release of protected health information (PHI)– the biological parent or the Court.

The *California Guidelines for the Use of Psychotropic Medication with Children and Youth in Foster Care* will be reviewed annually.

Challenges in Diagnosis and Prescribing of Psychotropic Medication

To address common challenges that occur in psychiatric diagnosis and prescribing, the guidelines provide additional recommendations that are categorized into three main topics: a) diagnosis clarity and substantiation, b) medication starts, and c) concurrent use of multiple medications (polypharmacy). Information can be found in Appendix C.

Guidelines for Prescribers of Psychotropic Medications[42],[43], [44]

The following questions and concerns may be helpful for prescribers to review before a decision to prescribe psychotropic medication is reached. Appendix D is a checklist for prescribers to facilitate such review.

Before prescribing, have the following concerns been considered:

- Might the existing treatment be exacerbating the child's behavior?

- Weigh the potential benefits and risks of psychotropic medication use against the risks of untreated illness.

- Caution is recommended in prescribing psychotropic medications to children and adolescents especially those for which long term consequences are incompletely understood.

- Are there evidence-supported non-pharmacological treatments appropriate for this child/youth available in the community?

- If non-pharmacological treatments been offered by an appropriately trained provider? If so, was the length of treatment adequate to evaluate treatment effectiveness, as evidenced by written documentation provided by the therapist?

- If there are no evidence-supported psychotherapeutic treatments appropriate for this child/youth available in the community, could other mental health interventions be tried?

- Are there environmental factors, e.g., in the placement or school setting, that could or should be addressed first?

- A consult with a psychiatric specialist is indicated if there is a question of neurological or medical conditions contributing to the child's symptoms or if medication is a possible component of treatment.

- Medication adherence is an important component of the treatment plan. As part of the informed consent and assent process, the prescriber discusses medication adherence with the youth and family, including the physical and behavioral consequences of abrupt withdrawal. Adverse effects should routinely be discussed as part of informed consent and assent.

- If there is concurrent substance abuse and prescription of psychotropic medication is being considered, the prescriber considers need for concurrent dual diagnosis (mental health and substance abuse) treatment to ensure concerns in both domains are addressed. Medications should be considered with care during events or situations which may be stressful or traumatic for a youth, such as the initial removal from the home, or a change of placement.

- When indicated, psychotropic medications are to be prescribed as part of a documented comprehensive treatment plan and not as the sole intervention. They are not prescribed in lieu of instituting available non-pharmacological treatments that are evidence-supported and that target the individual child's needs.

When prescribing, consider the following:

- Preference is given to FDA approved medications.

- "Off-label"[45] use of medications lack FDA scrutiny regarding their efficacy and safety. Widespread use in practice does not mean that "off-label" uses of medications are effective and safe.

- Is there a generic equivalent of medication available?

- Where ever possible prescribing decisions should be based on benefits that have been substantiated in high quality clinical studies.

- Different classes of psychotropic medications differ in their risk versus benefit profiles. Those classes with the greatest chance of adverse effects, particularly antipsychotic medications, should be used cautiously and reserved for clinical situations where there is a high level of confidence, based on published evidence, that potential benefits outweigh potential harms.

- Medication dosages should be kept within FDA guidelines for children when these are available. Any deviation from FDA guidelines is to be documented with the underlying rationale in the child's treatment records.

- Treatment with a single medication for a single symptom or disorder should be tried before treatment with multiple medications is considered.

- The use of two or more medications for the same symptom or disorder requires specific documentation from the prescribing clinician in the child's health record.

- In most circumstances, only one medication should be changed at one time.

- Medications should be initiated at a low dose and increase gradually only if there is a lack of response to medication. The clinical wisdom, "start low and go slow" is particularly relevant when treating children in order to minimize side effects and to observe for therapeutic effects.

- The decision to treat a child with more than one medication from the same class should be supported by written documentation in the child's health record from the prescribing clinician and may warrant a second review by a Child and Adolescent Psychiatrist.

- A clinician prescribing more than 1 psychotropic medication to one child should refer to Appendix A[46] for guidance.

- If this is not the first prescription for psychotropic medication for this child, periodic evaluation of treatment efficacy and tolerability should occur, as described above. At each subsequent appointment for medication management, this evaluation includes review of the following:

- Is there amelioration of symptoms of behavioral dyscontrol or emotional distress as assessed by clinical interview, collateral reports, validated assessment instruments (e.g., Beck Youth Inventories, Trauma Symptom Checklist for Children), and improved psychosocial functioning?

- Are target symptoms well controlled in at least one of the child's natural environments (excludes group homes and Residential Treatment Centers)?
- Are the medication dose and duration adequate?
- Has child/youth (or care environment as a whole) received appropriate evidence-supported psychotherapeutic treatments (if indicated)?
- Has the child/youth received informal psychosocial supportive interventions that promote development of resilience and learned control?
- What is the child/youth's perspective regarding the medication? Does the child/youth state that the medication is helpful?
- Do the observed therapeutic benefits to date outweigh the potential risks?
- Are there any medication adverse effects that indicate a need for tapering dosage and/or discontinuation?
- Efforts have been made to adjust medication dose to the minimum at which it remains effective and side effects are minimized. These efforts, or reasons why adjustments could not be considered, are documented in the youth's Treatment Plan and have been discussed with the youth and family.
- Periodic attempts at taking the child off medication have been tried or were determined to not be appropriate at this time. Efforts to discontinue the medication(s), or the rationale for continuing the medication, are documented in the child's Treatment Plan.
- The child/adolescent should be monitored for adverse effects, such as movement disorders, extreme weight gain or loss, and documentation should be present in the child's medical/psychiatric record.
- If adverse effects occur, tapering off the medication may be indicated, and identification of another clinically appropriate intervention is encouraged. These side (adverse) effects and efforts to taper and identify another clinically appropriate intervention are documented in the youth's Treatment Plan.
- The youth and family are consulted in discussions regarding tapering or discontinuing medication and identification of potential alternatives.

- Caution and pause should be used before treating side effects with the addition of medication. If used, the rationale is documented in the youth's Treatment Plan. The rationale also has been discussed with the youth and family; this discussion also is documented in the youth's Treatment Plan.

Prescribing in Emergency Situations

In emergency situations a child should be stabilized before a long-term medication plan is considered. During emergency situations to stabilize a child, consider the following:

a. Careful consideration should be placed on medication selection even during a psychiatric emergency.

b. One time or short term medication orders should state "no refills" as a safeguard and to prompt a re-evaluation before continuation occurs.

c. Before medications are started, a specific plan for tapering or consolidating the regimen should be developed. This plan should be clearly communicated to the follow-up provider or outpatient team.

d. In residential settings, the medication log should clearly indicate the medications used during the emergency with the doses, frequencies, and start/stop dates.

e. Court authorization must be sought as soon as practical but in no case more than two court days after the emergency administration of the psychotropic medication (California Rules of Court 5.640(i)).

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[46] Appendix A: Prescribing Standards for Psychotropic Medications.

Appendix A

Prescribing Standards of Psychotropic Medication Use by Age Group

Introduction:

The following prescribing standards are for use in reviewing a JV-220(A) application for the court. These prescribing standards represent the current state of best practices and incorporate current evidence-based support. These prescribing standards are not intended to stifle independent treatment or care by a provider. Rather, they are presented to form a foundation for review with the goal to ensure that youth being prescribed psychotropic medications receive the minimum number of medications necessary in the lowest therapeutic doses and for the appropriate age. Furthermore, it is the intent of these criteria to minimize incidences of inappropriate prescribing (overuse, underuse, inappropriate use), and to reduce exposure of children and youth to medication intervention that may not be appropriate (Reference 1).

In this document, “psychotropic medication”, or drugs are defined by the Cal. Code Regs. Tit. 22 51056.

At present the use of psychopharmacological agents in children and adolescents are intended to suppress symptoms and ameliorate maladaptive behaviors. They should be considered as one element in a comprehensive treatment plan along with other psychosocial and environmental interventions. Their potentially serious adverse effects must be considered and a plan for ongoing close monitoring of potential adverse effects be established based on monitoring parameters.

If the following prescribing standards are not met, the prescriptions are flagged. Prescribers will be asked to submit additional information for further review and approval.

Summary of allowable psychotropic medication by age group:

Age (years)	Number of psychotropic medications allowed
0-5	<2 (allows 1)
6-11	<3 (allows no more than 2)
12-17	<4 (allows no more than 3)

Prescribing Standards of Psychotropic Medication Use by Age Group:

Age in years	Prescribing Standards
12-17	<4 psychotropic medications a. <2 antipsychotics (any combination of atypical and typical) b. <2 mood stabilizers (anti-psychotics not included) c. <2 antidepressants (trazodone as hypnotic excepted) d. <2 stimulants (this does not include a long-activating stimulant and immediate-release stimulate that is the same chemical entity (e.g., methylphenidate-OROS and methylphenidate) e. <2 hypnotics (including trazodone, diphenhydramine, zolpidem and melatonin, benzodiazepines, not including clonidine, guanfacine, and prazosin) f. Medication dose(s) within the usual recommended dose(s) as defined in the most recent version of the State parameters (adaptation of the Los Angeles County Department of Mental Health's Parameters 3.8 For Use of Psychotropic Medication For Children and Adolescents. (Reference 2)
6-11	<3 psychotropic medications a. All other restrictions from above.
0-5	<2 psychotropic medications a. All other restrictions from above. b. Allows stimulant, atomoxetine, guanfacine, clonidine, or risperidone (for Autistic Spectrum Disorders and associated aggression) only.

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Appendix B

Parameters for Use of Psychotropic Medication for Children and Adolescents

Introduction:

The Los Angeles County Department of Mental Health (LACDMH), in December 2014, granted approval to the Department of Health Care Services (DHCS) and the California Department of Social Services (CDSS) the adoption of LACDMH *Parameters 3.8 for Use of Psychotropic Medication for Children and Adolescents* as Appendix B of the draft California Guidelines on Psychotropic Medication Use in Children and Adolescents in Foster Care.

Parameters 3.8 for Use of Psychotropic Medication for Children and Adolescents represents a consensus of best practices from among various experts from Los Angeles training institutions and experienced community based clinicians who provide treatment to children and adolescents. **The Parameters are updated quarterly to reflect improvements in evidence based treatments.**

By adopting the Los Angeles Department of Mental Health *Parameters 3.8 For Use of Psychotropic Medication for Children and Adolescents,* as part of California Guidelines, it is our goal to further disseminate these parameters for use throughout the state.

For the most up to date version of *Parameters 3.8 for Use of Psychotropic Medication for Children and Adolescents* scroll down to the Clinical Practice Parameters, select Medication Use, then select Psychotropic Medication in Children and Adolescents on the Los Angeles County Department of Mental Health Clinical Practice page.

DEPARTMENT OF MENTAL HEALTH

PARAMETERS MED-08
USE OF PSYCHOTROPIC MEDICATION IN CHILDREN AND ADOLESCENTS

January 19, 2022

INTRODUCTION

DMH Parameters Med-08 Use of Psychotropic Medication for Children and Adolescents, is designed primarily to assist treatment providers in the use of psychotropic medications as part of the overall treatment plan for diagnosed mental disorders in children and adolescents, up to 18 years of age, who receive mental health services through either directly-operated Los Angeles County Department of Mental Health clinics or the Department's contracted agencies. The use of psychotropic medications in early childhood is relatively infrequent; the use of such medications in children under the age of three is rare.

Nonclinical, nonmedical, or otherwise insufficiently trained individuals should take caution when reading this guide due to risks of misunderstanding, misusing, and misinterpreting its information and intent. Such individuals are advised to consult with the prescribing healthcare provider when questions and concerns arise.

This resource document was developed by consensus among a committee composed of various community-based clinicians and faculty from local training institutions who are experienced in psychiatric medication treatment of children and adolescents. It is updated periodically to reflect advancements in research and literature regarding evidence-based treatments. The document is not intended to imply standard of care. It is also not intended to be a narrowly prescriptive or comprehensive treatment document, nor to guide pharmacotherapy in children and adolescents whose treatment planning is complicated by the presence of special healthcare needs. Similarly, items listed under medical workup and follow-up, including laboratory tests, are intended to be considered based on particular clinical circumstances rather than being categorically required. Psychosocial treatments, which are sometimes first-line treatments of mental disorders and important considerations in the formulation of an overall treatment plan, are discussed in other sources. Various documents that may serve as additional resources are identified in the references section of this document.

Treatment provided outside of the parametric elements in this guide should have special justification and/or consultation with corresponding documentation of rationale in the medical record. Changes in current medication regimens made for the purpose of conforming with this guide should be initiated only after careful clinical consideration of the basis for the current medication regimen and potential risks of altering it. Non-adherence to medication treatment is a special situation to be considered and addressed by the prescribing healthcare provider. The health risks related to medication discontinuation and lack of medication treatment should be considered in further treatment planning.

Doses of medications in this guide are expressed by a dosage range, with the assumption that the prescribing healthcare provider adjust dosages used based on the individual circumstances of each patient. Dose ranges in this guide are not expressed by body surface area or in weight-adjusted doses, and they are not specifically calibrated or adjusted for children with compromised ability to metabolize and excrete these drugs. A discussion of potential metabolic variations due to ethnic/racial/genetic background is beyond the scope of this document.

*SECOND GENERATION ANTIPSYCHOTICS

A. Warnings for Concomitant Medication Use:
1. Drugs that lower plasma level: carbamazepine (CBZ), phenytoin (PHT), phenobarbital (PB), smoking
2. Drugs that increase plasma level: fluoxetine, fluvoxamine, paroxetine, macrolide antibiotic, cimetidine
3. Avoid >1 antipsychotic at a time

B. Medical Work-up (Baseline):
1. Physical exam (including height, weight, BMI, BP, pulse, dyskinesia)
2. Labs: fasting blood glucose, Hgb A1c, fasting lipid panel, liver enzymes, CBC + differential, UA, BUN, creatinine
3. Check for abnormal, involuntary movements
4. Baseline EKG (ziprasidone)

C. Medical Follow-up:
1. Each visit: Vitals, height, weight and as clinically indicated.
2. Wk 4, 8, 12 then annually: height, weight, BMI (compared against growth chart)
   - If rapid weight gain, high risk for DM, and/or below age 7: need weight management intervention with close monitoring of fasting blood glucose and fasting lipid panel
3. Two weeks after every dose titration up: BP, Pulse, EPS (rigidity, tremor, akathisia)
4. At least every 3 months: AIMS
5. Wk 12 then annually: fasting blood glucose, Hgb A1c, fasting lipid panel, liver enzymes, CBC + differential, BUN, creatinine (+ prolactin level, if clinically indicated for risperidone)
6. For clozapine: *per protocol*
7. For ziprasidone: repeat EKG after dose increases
8. If clinically indicated: pregnancy test

Relative risk of adverse side effects, from highest to lowest:	● *Diabetes/hyperlipidemia/ weight gain:*	clozapine ≥ olanzapine > quetiapine ≥ risperidone = paliperidone > asenapine > aripiprazole > lurasidone > ziprasidone
	● *Orthostatic hypotension:*	clozapine > risperidone = paliperidone > quetiapine > lurasidone > asenapine > olanzapine = aripiprazole > ziprasidone
	● *Sedation:*	clozapine > olanzapine > quetiapine > lurasidone > risperidone > paliperidone = asenapine > aripiprazole = ziprasidone
	● *Hyperprolactinemia:*	paliperidone > risperidone > olanzapine > ziprasidone, asenapine > quetiapine > lurasidone >> aripiprazole
	● *EPS:*	risperidone > paliperidone > lurasidone = aripiprazole = asenapine = ziprasidone > olanzapine >> quetiapine

DRUG NAME** + *Available dosage forms*	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	BOXED WARNING	COMPLICATIONS / PRECAUTIONS
aripiprazole (Abilify®): tablet, oral solution, oral disintegrating tablet	Psychosis Bipolar disorder, mania / mania with depressive episodes Aggression/irritability in Autism Spectrum D/O Tourette D/O	2 – 30 Age ≥ 4: Initial 2 Age 4 – 11: Max 15 Age ≥ 12: Max 30 <u>Tourette D/O</u>: Wt < 50 kg: Max 10 Wt ≥ 50 kg: Max 20	1 x/d	Nausea, vomiting weight gain, restlessness, psychomotor activation Higher rates of akathisia	↑ nausea, hypotension	Increased risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive D/O and other psychiatric D/O	**<u>Complications</u>:** - NMS - Withdrawal dyskinesis **<u>Precautions</u>:** - Liver disease - Respiratory distress - Pregnancy & breast feeding - Rare cases of DRESS: fever with rash, swollen lymph glands, face swelling - Requires immediate medical attention - Rare, but possible increase in risk of unexplained sudden death - Causality not established yet
quetiapine (Seroquel®): Tablet (crushable), XR tablet (do <u>not</u> crush)	Psychosis Bipolar disorder, mania	12.5 – 800 Age 5 – 9: Initial 12.5 – 25 Max 400 Age 10 – 17: Initial 25 mg **2x/d** Max 800	1 – 3 x/d XR: 1 x/d	Weight gain, ↑ lipids, ↑ glucose	Least EPS, ↑ prolactin, moderate hypotension <u>XR formulation</u>: Take while fasting or with a light meal (≤ 300 calories meal), preferably in the evening		

*SECOND GENERATION ANTIPSYCHOTICS *(Cont'd)*

DRUG NAME** + *Available dosage forms*	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	BOXED WARNING	COMPLICATIONS / PRECAUTIONS
lurasidone (Latuda®): tablet *(brand only)*	Psychosis Bipolar I Depression, monotherapy	20 – 80 <u>Psychosis</u> (13 – 17 y/o): 40 – 80 <u>Bipolar I Depression</u> (10 – 17 y/o): 20 – 80	1 – 2 x/d	Dyspepsia, sedation, wt gain, nausea, ↑ glucose EPS / TD	Take with food (> 350 calorie meal) **<u>Contraindication</u>:** - Avoid use with strong CYP3A4 inhibitors/inducers		**<u>Complications</u>:** - NMS - Withdrawal dyskinesis **<u>Precautions</u>:** - Liver disease - Respiratory distress - Pregnancy & breast feeding - Rare cases of DRESS: fever with rash, swollen lymph glands, swelling of the face - Requires immediate medical attention - Rare, but possible increase in risk of unexplained sudden death - Causality not established yet
clozapine (Clozaril®): tablet, oral disintegrating tablet, oral solution (Versacloz – *brand only*)	Treatment resistant psychosis Bipolar disorder Tardive dyskinesia Severe EPS	6.25 – 600 Age 8 – 11: Initial 6.25 – 12.5 Max 150 – 300 Age ≥ 12: Initial 6.25 – 25 Max 600	1 – 2 x/d	Agranulocytosis, seizures, constipation, salivation, myocarditis <u>Highest risk</u>: wt gain, ↑ lipids, ↑ glucose, sedation, hypotension, tachycardia, respiratory depression	- Consider when patient fails ≥ 2 trials of antipsychotics at adequate dose/duration - Target serum clozapine leve of ≥ 350 ng/mL for optimal efficacy **<u>Contraindications</u>:** - Myelosuppression - Uncontrolled seizure disorder	- Severe neutropenia - Seizures - Orthostasis, bradycardia, syncope - Myocarditis, cardiomyopathy Mitral valve incompetence	
olanzapine (Zyprexa®): tablet, oral disintegrating tablet, IM injection	Psychosis Bipolar disorder	1.25 – 20 Age 4 – 5: Initial 1.25 Max 12.5 Age 6 - 12: Initial 2.5 Max 20 Age ≥ 13: Initial 2.5 – 5 Max 20	1 – 2 x/d	Weight gain, ↑ lipids, ↑ glucose, ↑ prolactin, tachycardia, restlessness EPS / TD	<u>Not</u> recommended to try as first-line treatment option due to high risk of significant weight gain (diabetes, hyperlipidemia)	None related to youth	

*SECOND GENERATION ANTIPSYCHOTIC *(Cont'd)*

DRUG NAME** + *Available dosage forms*	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	BOXED WARNING	COMPLICATIONS / PRECAUTIONS
risperidone (Risperdal®): Tablet (crushable), oral disintegrating tablet, oral solution	Psychosis Bipolar disorder, mania / mania with depressive episodes Aggression/irritability in Autistic Spectrum D/O	0.25 – 6 Age 4 – 5: Wt < 20 kg: Initial 0.25 Wt ≥ 20 kg: Initial 0.5 Age ≥ 6: Initial 0.5 Age 4 – 11: Max 3 Age ≥ 12: Max 6	1 – 2 x/d	Weight gain, ↑ lipids, ↑ glucose, ↑ prolactin, tachycardia, restlessness, hypotension (high risk) Highest risk of EPS / TD and hyperprolactinemia			**Complications:** - NMS - Withdrawal dyskinesis **Precautions:** - Liver disease - Respiratory distress - Pregnancy & breast feeding - Rare cases of DRESS: fever with rash, swollen lymph glands, swelling of the face → Requires immediate medical attention - Rare, but possible increase in risk of unexplained sudden death → Causality not established yet
paliperidone (Invega®): ER tablet (do not crush)	Psychosis	3 – 12 Age ≥ 12: Initial 3 Wt < 51 kg: Max 6 Wt ≥ 51 kg: Max 12	1x/d	Weight gain, ↑ lipids, ↑ glucose, ↑ prolactin, somnolence, tachycardia EPS / TD	- Active metabolite of risperidone - Limited hepatic metabolism - Potential for ghost tablet in stool		

*SECOND GENERATION ANTIPSYCHOTIC *(Cont'd)*

DRUG NAME** + *Available dosage forms*	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	BOXED WARNING	COMPLICATIONS / PRECAUTIONS
ziprasidone (Geodon®): capsule, IM injection	Psychosis Bipolar disorder	20 – 160 Age 10 – 17: Initial 20 Wt ≤ 45 kg: Max 80 Wt > 45 kg: Max 160	1 – 2 x/d	Nausea, headache, prolongation of QTc EPS / TD	- Take with food (≥ 500 calorie meal) - Lowest risk of: wt gain, EPS, hypotension, sedation **Contraindications (CI):** - Avoid use in patients with congenital long QT syndrome, current/history of QTc prolongation, or CVD/uncompensated heart failure Avoid use with concurrent med that ↑ QTc	None related to youth	**Complications:** - NMS - Withdrawal dyskinesis **Precautions:** - Liver disease - Respiratory distress - Pregnancy & breast feeding - Rare cases of DRESS: fever with rash, swollen lymph glands, swelling of the face → Requires immediate medical attention - Rare, but possible increase in isk of unexplained sudden death → Causality not established yet

Not included/recommended due to insufficient evidence in youth: **Iloperidone (Fanapt®)**

Not approved for children/adolescents and insufficient evidence: **brexpiprazole (Rexulti®), cariprazine (Vraylar®), lumateperone (Caplyta®)**

* *Not indicated for insomnia*
** *Common brand name is indicated for convenience. No preference is implied*
*** *Maximum doses based on literature*

EPS *Extrapyramidal Symptoms*

TD *Tardive Dyskinesia*
NMS *Neuroleptic Malignant Syndrome*
DRESS *Drug Reaction with Eosinophilia and Systemic Symptoms*
AIMS *Abnormal Involuntary Movement Scale*

LONG-ACTING ANTIPSYCHOTIC INJECTIONS

A. Criteria for Use:

1. Must demonstrate positive response and tolerability to oral form of medication
2. No history of NMS
3. Maintenance antipsychotic therapy
4. Prevention of non-adherence related relapse
5. Effective medication delivery (if oral/GI delivery is not feasible)
6. Insufficient data to support safe use under age 18

B. Medical Work-up and Follow-up:
Refer to oral formulation of drug

C. Complications/Precautions:
Refer to oral formulation of drug

D. Adverse Effects:
Refer to oral formulation of drug

DRUG	FORMULATION	STRENGTHS SUPPLIED	DOSE (mg/d)	DOSAGE SCHEDULE	PO OVERLAP	SPECIAL CONSIDERATIONS
haloperidol decanoate (Haldol Decanoate®)	esterified with decanoic acid, (sesame) oil base	50 mg/mL 100 mg/mL	50 - 200	4 weeks	3 - 4 weeks	Additional contraindication: Hypersensitivity to sesame oil Similar warnings and side effects as oral haloperidol Less frequent EPS Inflammation & nodule at injection site (less common if deltoid used and lower concentration is used)
fluphenazine decanoate (Prolixin Decanoate®)	esterified with decanoic acid, (sesame) oil base	25 mg/mL	12.5 - 40	2 - 4 weeks	Varies	Additional contraindication: Hypersensitivity to sesame oil Similar warnings and side effects as oral fluphenazine More frequent EPS (up to 50%) due to early peak serum level, dermatological reaction been reported, EKG changes in some patients, hematologic changes within normal variation
risperidone (Risperdal-Consta®)	encapsulated microspheres, aqueous base	12.5 mg/vial 25 mg/vial 37.5 mg/vial 50 mg/vial *must draw up entire vial	12.5 - 50	2 weeks	3 weeks	Similar warnings and side effects as oral risperidone Akathisia & parkinsonism (7%), hyperkinesia (12%), pain, redness, swelling at injection site (<5%)
paliperidone palmitate (Invega Sustenna®)	multi-sized particles in nanosuspension, aqueous base	39 mg/0.25mL 78 mg/0.5mL 117 mg/0.75mL 156 mg/mL 234 mg/1.5 mL	39 - 234	4 weeks	1 - 2 weeks	Need to initiate with 234 mg on day 1, then 156 mg on day 8 (both loading doses should be given in deltoid) Similar warnings and side effects as oral paliperidone Induration, redness, swelling at injection site (>7%)
aripiprazole monohydrate (Abilify Maintena®)	lyophilized, aqueous base	300 mg 400 mg in prefilled syringes or vials	200 - 400	4 weeks	2 weeks	Similar warnings and side effects as oral aripiprazole Weight gain, akathisia, injection site pain, sedation Usual dose 400 mg, but adjusted to 200-300 mg if on concurrent CYP3A4/2D6 inhibitors
aripiprazole lauroxil (Aristada®)	non-ester prodrug of aripiprazole, aqueous base	441 mg/1.6 mL 662 mg/2.4mL 882 mg/3.2 mL 1064 mg/3.9 mL	441-1064	4 - 8 weeks	3 weeks	Gluteal IM administration only for doses >441 mg Similar warnings and side effects as oral aripiprazole Akathisia, pain, induration, swelling, redness at injection site (<4%)

ANTIPARKINSON / ANTICHOLINERGICS

A. Clinical Indications For Use:
medication induced extrapyramidal dysfunctions (Parkinson's syndrome, dystonia, akathisia, dyskinesia)

B. Frequency of Dose Change:
1. if clinically indicated
2. may be withdrawn after a few days to 3 months of use to observe for EPS and assess need for use.

C. Concomitant Medication Use:
1. use only one of this class at a time
2. avoid use with other parasympatholytic agents (TCA's, low potency antipsychotics)

D. Complications & Side Effects:
1. confusion, disorientation, delirium, hallucinations, cognitive dulling, impaired memory
2. constipation, visual accommodation, tachycardia, xerostomia, pupillary dilatation, flushed-dry-hot skin, headache, coma, death
3. worsening of pre-existing psychotic symptoms
4. aggravation of asthma
5. abuse potential: may produce a “buzz”
6. hyperthermia

E. Cautions/Contraindications:
1. age < 3 y/o
2. exposure to heat, severe physical stress
3. closed angle glaucoma
4. obstructive bowel d/o, megacolon

F. Medical Work-up:
1. none suggested

G. Medical Follow-up:
1. if clinically indicated

DRUG (Common brand name is indicated for convenience. No preference is implied.)	DOSE (mg/d)	DOSAGE SCHEDULE	SPECIAL CONSIDERATIONS
benztropine (Cogentin®)	0.25 - 6	1-2 x/d	available by injection
Trihexyphenidyl (Artane®)	0.50 - 6	2-3 x/d	abuse potential

ANTIHISTAMINES

A. Clinical Indications For Use:
1. Anxiolytic/sedative/hypnotic
2. allergic reactions
3. motion sickness

B. Frequency of Dose Change;
daily as indicated

C. Complications & Side Effects:
See Antiparkinson / Anticholinergic

D. Concomitant Medication Use:
1. avoid use with other parasympatholytic agents (TCA's, low potency antipsychotics)
2. avoid MAOI's
3. potentiates barbiturates, alcohol, tranquilizers, opiates

E. Cautions/Contraindications:
1. See Antiparkinson / Anticholinergic
2. age < 1 y/o

F. Medical Work-up:
1. none suggested

G. Medical Follow-up:
1. if clinically indicated

DRUG (Common brand name is indicated for convenience. No preference is implied.)	DOSE (mg/d)	DOSAGE SCHEDULE	SPECIAL CONSIDERATIONS
Diphenhydramine (Benadryl®)	12.5 - 150	1-4 x/d	tablet, capsule, liquid, IM or IV
hydroxyzine pamoate (Vistaril®) hydroxyzine HCl (Atarax®)	12.5 - 300	1-4 x/d	capsule, tablet, syrup

PSYCHOSTIMULANTS

A. Clinical Indications For Use:

1. Attention-Deficit/Hyperactivity Disorder
2. attention deficit symptoms associated with other mental disorders

B. Frequency of Dose Change:

No more than two (2) changes in any 7-day period.

C. Concomitant Medication Use:

1. Only one psychostimulant at any one time.
2. No heterocyclic antidepressant unless trials of individual meds have failed
3. No MAO inhibitors

D. Complications & Side Effects:

1. agitation, irritability, hyperactivity
2. exacerbation of obsessions and compulsions
3. insomnia, decreased appetite, weight loss, delayed growth
4. increased heart rate & blood pressure
5. agitation, irritability
6. dyskinetic movements/tics
7. depression or psychosis in high doses
8. withdrawal effect or rebound phenomena

E. Cautions/Contraindications:

1. alcohol or drug abuse
2. anorexia nervosa
3. psychoses
4. severe anxiety
5. hx of cardiovascular disease or family hx of cardiovascular disease, including structural heart defects, or unexplained sudden death

E. (cont) Cautions/Contraindications:

6. thyroid disease
7. glaucoma
8. pregnancy & breast feeding
9. allergy to the drug

F. Medical Work-up:

1. physical exam (incl. ht, wt, on graph)
2. EKG at baseline if positive cardiac risk factors

G. Medical Follow-up:

1. BP, pulse: periodic or when clinically indicated
2. periodic: height & weight (graph)
3. annual: physical exam

DRUG (Common brand name is indicated for convenience. No preference is implied.)	DURATION OF EFFECT	DOSE (mg/d)	DOSAGE SCHEDULE	SPECIAL CONSIDERATIONS
dextroamphetamine (Dexedrine®, Dextrostat®, Liquadd®)	4-5 hours	2.5 - 40	1-3 x/d	Liquadd® avail in liquid form
amphetamine salts (Adderall®) *	4-5 hours	2.5 - 60	1-3 x/d	
methylphenidate (Ritalin®, Methylin®, Metadate®)	4-5 hours	2.5 - 60	1-3 x/d	Methylin® avail in liquid form
dexmethylphenidate (Focalin®)	3-5 hours	2.5 - 40	1-3 x/d	
INTERMEDIATE ACTING				
methylphenidate (Ritalin SR®, Metadate ER®, Methlyn ER®)	6-8 hours	2.5 - 60	1-2 x/d	Must be swallowed whole
methylphenidate (Metadate CD®)	8-9 hours	10 - 60	Once daily	Sprinkle on food as long as bead swallowed whole
methylphenidate (Ritalin LA®) - capsule	8-10 hours	10 - 60	Once daily	Sprinkle on food as long as bead swallowed whole. High fat food may delay absorption

PSYCHOSTIMULANTS *(Cont'd)*

DRUG (Common brand name is indicated for convenience. No preference is implied.)	DURATION OF EFFECT	DOSE (mg/d)	DOSAGE SCHEDULE	SPECIAL CONSIDERATIONS
methylphenidate patch (Daytrana®)	as long as patch applied + up to 3 hours	10 - 30	Once daily for 9 hrs	Skin irritation, remove after 9 hours; persistent loss of skin color (chemical leukoderma)
Methylphenidate (Concerta®)	8-12 hours	18 - 72	Once daily	Must be swallowed whole. Inert portion of tablet may appear in stool
Methylphenidate (Quillivant XR®)	8-12 hours	10 - 60	Once daily	Must be reconstituted with water.
Dexmethylphenidate (Focalin XR®) - capsule	12 hours	5 - 40	Once daily	Can sprinkle on food as long as Bead swallowed whole
amphetamine salts (Adderall XR®) - capsule	10-12 hours	5 - 60	Once daily	Can sprinkle on food as long As bead swallowed whole
Lisdexamfetamine (Vyvanse®) ** not to be ingested with citric products*	10-12 hours	20 - 70	Once Daily	Can be dissolved in water to drink immediately

SELECTIVE NOREPINEPHRINE REUPTAKE INHIBITORS

DRUG	MAIN INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	CAUTIONS/ CONTRAINDICATIONS
atomoxetine (Strattera®)	ADHD	10 – 100	1-2 x/d	decreased appetite, gastrointestinal sx, palpitations, mood swings, rare hepatoxicity	MAOI's, pressor agents, albuterol, narrow angle glaucoma

ALPHA-ADRENERGIC AGONISTS

A. Clinical Indications For Use:

1. Attention-Deficit/Hyperactivity Disorder
2. agitation, impulsive aggression, impulsivity
3. Tic D/O
4. PTSD

B. Frequency of Dose Change:

No more than two (2) changes in any 7-day period.

C. Concomitant Medication Use:

1. Only one alpha-adrenergic agonist at any one time.
2. No MAO inhibitors

D. Complications & Side Effects:

1. sedation
2. decreased blood pressure
3. dizziness
4. rebound hypertension on discontinuation
5. constipation
6. headache
7. dry eyes

E. Cautions/Contraindications:

1. pregnancy & breast feeding
2. hx of cardiovascular disease and family hx of cardiovascular disease or unexplained sudden death
3. dosage adjustment for renal insufficiency

F. Medical Work-up:

1. physical exam
2. EKG at baseline if positive cardiac risk factors

G. Medical Follow-up:

1. At each dosage change: orthostatic BP, pulse,
2. annual: physical exam
3. Repeat EKG if clinically indicated

H. Dosing for guanfacine ER (Intuniv®)

0.05-0.12 mg/kg/dose PO qd

DRUG (Common brand name is indicated for convenience. No preference is implied.)		MAIN INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS
clonidine	(Catapres®)	see class	0.05 - 0.60	1-4 x/d		cautious use in combination with psychostimulants
	patch (Catapres®) TTS-1, 2 or 3	see class	0.10 - 0.60	1 patch/wk	localized dermatitis fatal overdose if ingested	cautious use in combination with psychostimulants
	extended release (Kapvay®)		0.1 – 0.4	bid	URI sxs; mood sxs irritability, sore throat, trouble sleeping (insomnia), nightmares, change in mood, and ear pain	adjunctive tx with psychostimulants
guanfacine	(Tenex®)	see class	1 - 4.0	1-3 x/d		cautious use in combination with psychostimulants
	(Intuniv®) extended release	see class	1-7 (see dosing above)	1/d		adjunctive tx with psychostimulants

TRICYCLIC ANTIDEPRESSANTS*

A. Warnings for Concomitant Medication Use:

1. Contraindicated in use with or within 14 days of discontinuing MAOI
2. Risk of serotonin syndrome with linezolid
3. Drugs that cause QT prolongation

B. Frequency of Dose Change:

No more than two (2) changes in any 7-day period

Medical Work-up:

1. Physical exam (including height, weight, blood pressure, pulse)
2. Labs: CBC + differential, liver enzymes, UA
3. EKG at baseline

D. Medical Follow-up:

1. Annual: Physical exam
2. EKG at steady state after each dose increase
3. If clinically indicated: Pulse, blood pressure, CBC + differential, liver enzymes, pregnancy test

DRUG NAME** + *Available dosage forms*	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
imipramine (Tofranil®) tablet, capsule	**FDA-approved Indication:** - Enuresis (age ≥ 6) **Other Clinical Use:** Not first line for depressive disorders	25 - 100 Max for 6-12 y/o: 2.5 mg/kg/day Enuresis: Max: 2.5 mg/kg/day or Age 6-11: 50 Age 12: 75	1-4 x/d 1 x/d for capsules	- Sedation - Dizziness - Syncope - Urinary retention - Constipation - Blurry vision - Dry mouth - ↓ seizure threshold - Weight gain	Most well-studied for enuresis in low doses Limited evidence on efficacy and safety for use in age ≤ 12 for depression May convert to imipramine pamoate capsules after reaching 75 mg/day on tablets	**Complications**: - Cardiac conduction abnormalities - Activation of mania/hypomania - Discontinuation syndrome - Overdose may be lethal - Agranulocytosis - Orthostatic hypotension **Precautions**: - Cardiac disease (including family history) - History of suicide attempts - Seizure disorder - Pregnancy - Breast feeding
desipramine (Norpramin®) tablet	Not first line for depressive disorders or ADHD	25 - 150 Max for 6-12 y/o: 3.5 mg/kg/day ADHD (age ≥ 5): Max: 3.5 mg/kg/day	1-4 x/d		Most well-studied for ADHD, sudden death reported Limited evidence on efficacy and safety for use in age ≤ 12 for depression	
amitriptyline (Elavil®) tablet	Enuresis Not first line for depressive disorders	2.5 - 150 Enuresis: Age 6-10: 25 Age ≥ 11: 50	1-4 x/d		Limited evidence on efficacy and safety for use in age ≤ 12 for depression High sedation, dry mouth and constipation	
nortriptyline (Pamelor®) capsules, oral solution	Not first line for depressive disorders	10 - 50	1-4 x/d		Limited evidence on efficacy and safety for use in age ≤ 12 for depression Least orthostasis Therapeutic blood level 60-100 ng/ml	
doxepin (Sinequan®) capsules, tablet, oral solution	Not first line for depressive disorders	10 - 100 Max: 3 mg/kg/day	1-4 x/d		Limited evidence on efficacy and safety for use in age ≤ 12 for depression Highest antihistamine effects Dilute oral solution in 120 mL of water, milk, orange, or tomato juice. Do not dilute in carbonated beverages	
clomipramine (Anafranil®) capsules	-	25 - 200 Max:3 mg/kg/day or 200 mg/d, whichever is smaller	1-4 x/d		Give with food to minimize GI upset	

** Antidepressants may increase suicidality (thoughts or behaviors) in children, teenagers and young adults when first started. Higher initial starting doses pose a greater risk of suicidality compared to lower initial starting doses (1% vs 0.5%). Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Not treating depression puts children, teenagers, and young adults at higher risk for suicide than treatment with antidepressants. ** Common brand name is indicated for convenience. No preference is implied *** Maximum doses based on literature*

SELECTIVE SEROTONIN REUPTAKE INHIBITORS*

A. Warnings for Concomitant Medication Use:

1. SSRIs that have a higher potential to increase the therapeutic levels of other medications
   a. fluvoxamine, fluoxetine, paroxetine
2. Contraindicated in use with or within 14 days of discontinuing MAOI
3. Washout period before starting MAOI
   a. 5 weeks after fluoxetine
   b. 2 weeks after sertraline, fluvoxamine, citalopram
   c. 1 week after paroxetine
4. No tryptophan

B. Frequency of Dose Change:

No more than two (2) changes in any 14-day period

C. Medical Work-up (Baseline):

1. Physical exam (including height, weight, BMI, blood pressure, pulse)
2. Lab: Liver enzymes, CBC + differential, UA, TSH
3. Additional labs to consider: vitamin D, B12, folate, zinc, magnesium

D. Medical Follow-up:

1. Annual: physical exam
2. If clinically indicated: CBC + differential, liver enzymes, serum sodium (hyponatremia symptoms), pregnancy test, abnormal involuntary movements, signs of abnormal bleeding

DRUG NAME** + Available dosage forms	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
fluoxetine (Prozac®) capsule, oral solution (mint flavor)	**FDA-approved Indications:** - Major depressive disorder (Age ≥ 8) - OCD (Age ≥ 7) **Other Clinical Uses:** - Adjunct with olanzapine in bipolar I disorder (Age ≥ 10) - Panic D/O (Age ≥ 8) - Generalized anxiety disorder (Age ≥ 7) - Social anxiety disorder (Age ≥ 7) - Bulimia nervosa (Age ≥ 12) - Separation anxiety disorder (Age ≥ 9) - Bulimia (Age ≥18)	5 - 60 Age 6 - 11: Initial 5 - 10 Age ≥ 12: Initial 10 Max: 60	1 x/d	- Nausea/Vomiting - Diarrhea - Dry mouth - Dyspepsia - Constipation - Dizziness - Drowsiness - Insomnia - Agitation, restlessness - Weight gain or loss - Anorexia - Headache - Sweating - Sexual dysfunction	Has most efficacy and safety data for use in children and adolescents Higher incidence of insomnia, dose in the morning Higher incidence of weight loss and anorexia	**Complications**: - Activation of mania/hypomania - Discontinuation Syndrome - Abnormal bleeding - Hyponatremia - QTc prolongation (citalopram, escitalopram, sertraline, fluoxetine) - Obesity - Akathisia - Serotonin syndrome (especially with concurrent serotonergic medications) **Precautions:** - Liver disease - Cardiac disease (citalopram, escitalopram, sertraline, fluoxetine) - Pregnancy - Breastfeeding
sertraline (Zoloft®) tablet, oral solution (menthol flavor, must be diluted before use)	**FDA-approved Indications:** - OCD (Age > 6) **Other Clinical Uses:** - Major depressive disorder (Age > 6) - Anxiety disorders (social, generalized, and separation anxiety, age > 7) - Panic disorder (Age > 8)	12.5 - 200 Age 6 - 12: Initial 12.5 - 25 Age 13 - 17: Initial 25 - 50 Max: 200	1-2 x/d		Give with food to minimize GI upset and improve absorption Higher incidence of nausea/vomiting and weight gain Caution in urine drug screens, reports of false positives for benzodiazepines in patients receiving sertraline	
paroxetine (Paxil®)	**Other Clinical Uses:** - OCD, panic disorder (Age > 7) - Social anxiety disorder (Age > 8)	10 - 50	1-2 x/d		Higher propensity for suicidality High risk of discontinuation syndrome, requires a slow taper	

tablet, oral suspension (orange flavor)						

DRUG NAME** + Available dosage forms	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
fluvoxamine (Luvox®) tablet, capsule (extended release)	**FDA-approved Indications:** OCD (Age ≥ 8) **Other Clinical Uses:** Anxiety disorders (social, generalized and separation anxiety, age > 6)	25 - 300 Age 8 - 11: Max 200 Age 12 - 17: Max 300	1-2 x/d IR: dose 2 x/d if daily dose >50 mg	- Nausea - Diarrhea - Dry mouth - Dyspepsia - Constipation - Dizziness - Sleep disturbance - Agitation, restlessness - Weight gain or loss - Anorexia - Headache - Sweating - Sexual dysfunction	Dose at bedtime for improved tolerability High drug interaction risk Higher incidence of weight loss, hyperkinesis Higher risk of discontinuation syndrome, requires slower taper	**Complications**: - Activation of mania/hypomania - Discontinuation Syndrome - Abnormal bleeding - Hyponatremia - QTc prolongation (citalopram, escitalopram, sertraline, fluoxetine) - Obesity - Akathisia - Serotonin syndrome (especially with concurrent serotonergic medications) **Precautions:** - Liver disease - Cardiac disease (citalopram, escitalopram, sertraline, fluoxetine) - Pregnancy - Breastfeeding
citalopram (Celexa®) tablet, oral solution (mint flavor)	**Other Clinical Uses:** - Major depressive disorder (Age ≥ 7) - OCD (Age ≥ 6) - Social anxiety disorder (Age ≥ 8)	5 – 40 Age 6 - 11: Initial 10 Age ≥ 12: Initial 20 Max: 40	1 x/d		Lower drug interaction risk QT prolongation risk increases when > 40 mg/day	
escitalopram (Lexapro®) tablet, oral solution (mint flavor)	**FDA-approved Indications:** - Major depressive disorder (Age ≥ 12) **Other Clinical Uses:** - Social anxiety disorder (Age ≥ 10) - Irritability in Autistic disorder (Age ≥ 6)	5 - 20 Age 6 - 11: Initial 5 Max 20 Age ≥ 12: Initial 10 Max 30	1 x/d		Higher incidence of weight gain Lower drug interaction risk	

Antidepressants may increase suicidality (thoughts or behaviors) in children, teenagers and young adults during initiation. Higher initial starting doses pose a greater risk of suicidality compared to lower initial starting doses (1% vs 0.5%). Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Not treating depression puts children, teenagers, and young adults at higher risk for suicide than treatment with antidepressants.

*** Common brand name is indicated for convenience. No preference is implied*

**** Maximum doses based on literature*

SEROTONIN & NOREPINEPHRINE REUPTAKE INHIBITORS*

A. Warnings for Concomitant Medication Use:

1. Contraindicated in use with or within 14 days of discontinuing MAOI
2. Risk of serotonin syndrome with linezolid

B. Frequency of Dose Change:

No more than two (2) changes in any 7-day period

C. Medical Work-up (Baseline):

1. Physical exam (including height, weight, blood pressure, pulse)
2. Labs: Liver enzymes, UA, TSH
3. Additional labs to consider: vitamin D, B12, folate, zinc, magnesium

D. Medical Follow-up:

1. Annual: Physical exam
2. Blood pressure during dosage titration
3. If clinically indicated: Pulse, blood pressure, liver enzymes, pregnancy test

DRUG NAME** + *Available dosage forms*	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
duloxetine (Cymbalta®) delayed-release capsules	**FDA-approved Indications:** - Generalized anxiety disorder (Age ≥ 7) - Fibromyalgia pain (Adolescents)	30 - 60 Max: 120 Fibromyalgia: Max: 60	1-2 x/d	- Headache - Insomnia - Somnolence - Fatigue - Dizziness - Nausea - Dry mouth - Anorexia - Weight loss or gain - Skin reaction	Cymbalta® and generic capsules: Swallow whole Drizalma® Sprinkle capsules: May open and sprinkle over cool applesauce	**Complications**: - Serotonin discontinuation syndrome - Activation of mania/hypomania - Severe skin reactions - Abnormal bleeding - Hepatotoxicity - Hyponatremia - Elevated blood pressure and pulse - Serotonin syndrome (especially with concurrent serotonergic medications) **Precautions**: - History of suicide attempts - Seizure disorders - Liver disease - Pregnancy - Breastfeeding
venlafaxine (Effexor®) tablets, extended-release tablets, extended-release capsules	Third line for depressive and anxiety disorders	12.5 – 225 Max dose: Wt 20 - 33 kg: 112.5 Wt 34 - 49 kg: 150 Wt ≥ 50 kg: 225	1-3 x/d		Limited evidence on efficacy and safety for use in age <18 for anxiety disorders Higher risk for suicidality, serotonin discontinuation syndrome, nausea, and dose-related hypertension Give w/ food to minimize GI upset Extended-release tabs/caps: Swallow whole	

***Antidepressants may increase suicidality (thoughts or behaviors) in children, teenagers and young adults when first started.** Higher initial starting doses pose a greater risk of suicidality compared to lower initial starting doses (1% vs 0.5%). Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Not treating depression puts children, teenagers, and young adults at higher risk for suicide than treatment with antidepressants.*

*** Common brand name is indicated for convenience. No preference is implied*

**** Maximum doses based on literature*

OTHER ANTIDEPRESSANTS*

A. Warnings for **Concomitant Medication Use:**
1. Contraindicated in use with or within 14 days of discontinuing MAOI
2. Bupropion - Drugs that lower seizure threshold

B. Frequency of Dose Change:
No more than two (2) changes in any 7-day period

C. Medical Work-up:
1. Physical exam (including height, weight, blood pressure, pulse)
2. Labs: CBC, fasting lipid panel, liver enzymes, UA, TSH
3. Additional labs to consider: vitamin D, B12, folate, zinc, magnesium

D. Medical Follow-up:
1. Annual: Physical exam
2. Blood pressure during dosage titration
3. CBC periodically
4. If clinically indicated: Pulse, blood pressure, liver enzymes, pregnancy test

DRUG NAME** + *Available dosage forms*	CLINICAL INDICATIONS	DOSE*** (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
bupropion (Wellbutrin®), bupropion SR, bupropion XL tablets	Alternative for ADHD (age ≥ 6) Not first line for depressive disorders	Initial: 3 mg/kg/day Maximum: IR: 6 mg/kg/day or 300, whichever is less SR: 400 XL: 450 Max 200 per dose for IR, SR	IR: 1-3 x/d SR: 2 x/d XL: 1 x/d	- Agitation - Headache - Insomnia - ↓ seizure threshold - Weight loss	**Contraindications:** - Seizure disorder - Eating disorder Limited evidence on dosing and safety for use in age < 18 for depression Take early in day to prevent insomnia	**Complications**: - Activation of mania/hypomania - Discontinuation syndrome **Precautions**: - History of suicide attempts - Active drug/alcohol abuse
mirtazapine (Remeron®) tablets, oral disintegrating tablets (orange flavor, 7.5 mg strength unavailable)	Not first line for depressive disorders	7.5 - 45	1 x/d	- Increased appetite - Drowsiness - Weight gain - Hyperlipidemia	**Complications**: - Agranulocytosis - Liver injury **Precautions**: - Liver disease Limited evidence on efficacy and safety for use in age <18	**Complications**: - Activation of mania/hypomania - Discontinuation syndrome - Abnormal bleeding - Hyponatremia **Precautions**: - History of suicide attempts
trazodone (Desyrel®) tablets	Insomnia Not first line for depressive disorders	25 - 400 Insomnia: Max: 200 Major depression: Max: 6 mg/kg/day	1-2 x/d	- Orthostatic hypotension - Dizziness - Sedation - Constipation	**Complications:** - QT prolongation, risk of sudden cardiac death - Priapism - Cognitive and motor impairment Reports of anxiety, irritability, dysphoria with high levels of trazodone metabolite in adolescents	

***Antidepressants may increase suicidality (thoughts or behaviors) in children, teenagers and young adults when first started. Higher initial starting doses pose a greater risk of suicidality compared to lower initial starting doses (1% vs 0.5%). Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Not treating depression puts children, teenagers, and young adults at higher risk for suicide than treatment with antidepressants.*

*** Common brand name is indicated for convenience. No preference is implied*

**** Maximum doses based on literature*

MOOD STABILIZER - lithium

A. Clinical Indications For Use:

FDA-approved indications:

1. bipolar disorder (Age ≥ 7)

Other clinical uses:

1. schizoaffective disorder
2. refractory depression (as adjunct when antidepressant alone is not effective) refractory impulsive aggression

B. Concomitant Medication Use:

1. Diuretics, ACE-Inhibitors/ARB and routine non-steroidal anti-inflammatory drugs (e.g., ibuprofen, celecoxib) usage can increase blood drug level to toxic range
2. Cautious use of serotonergic agents, concomitant mood stabilizers, and antipsychotics

C. Medical Work-up (Baseline):

1. Physical exam (including height and weight)
2. Labs: basic metabolic panel, CBC w/ differential, urinalysis, TSH
3. Consider EKG with multiple medications and relevant history and medical conditions

D. Medical Follow-up:

1. Annual: Physical exam, basic metabolic panel (serum creatinine), CBC
2. Serum levels 5-7 days after initiation or each dosage change
3. Every 6 months: weight, serum trough level, TSH
4. If clinically indicated: pregnancy test, repeat EKG after therapeutic level achieved

AVAILABLE DOSAGE FORMS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	BOXED WARNING	COMPLICATIONS/ PRECAUTIONS
lithium carbonate:capsules, ER tablets lithium citrate: oral solution (raspberry flavor, sugar free, alcohol 0.3%, 8mEq/5mL)	Weight 20-30 kg: Initial 600 (or 16mEq/day) Weight > 30 kg: Initial 900 (or 24mEq/day) Goal serum levels: Acute mania 0.8-1.2mEq/L Maintenance 0.8-1mEq/L	1-3 x/d	- polyuria - polydipsia - tremor - nausea/vomiting - diarrhea - decreased appetite - rash/dermatitis - thyroid abnormalities - dizziness - ataxia	Higher risk for side effects/complications for age < 13 years Caregiver should verify adequate fluid and food intake Serum levels should be collected 12 hours post-dose Lithium carbonate 300mg = lithium citrate 8mEq	Lithium toxicity - Increased risk with dehydration, significant renal dysfunction, cardiovascular disease, sodium depletion, febrile illness, elevated serum levels (>1.5 mEq/L) - Signs: ataxia, coarse tremor, vomiting, lethargy, blurred vision, slurred speech, stupor, confusion, delirium	**Complications:** - Hypothyroidism - Chronic kidney disease - Hyponatremia - EPS (with concurrent antipsychotic) - Serotonin syndrome (with concurrent serotonergic agents) **Precautions:** - Cardiovascular disease - Pregnancy - Breastfeeding

MOOD STABILIZER – antiseizure agents

A. Concomitant Medication Use:

1. CBZ - decreases serum levels of CYP3A4 substrates (see Appendix), efficacy of hormonal contraceptives may be decreased, CBZ levels may be increased by CYP3A4 inhibitors

2. VPA – increases lamotrigine serum levels (see Appendix)

B. Medical Work-up (Baseline):

1. Physical exam (including height, weight, and blood pressure)
2. Labs: complete metabolic panel (including liver function test), CBC w/ differential, pregnancy test
3. Consider EKG with CBZ and LTG if clinically indicated
4. Consider HLA-B*1502 (for Asian descent) and HLA-A*3101 tests for CBZ

C. Medical Follow-up:

For CBZ, VPA:

1. Annual: Physical exam, CBC w/ differential, complete metabolic panel
2. CBC w/ differential, liver function tests: q3mos for the first 6 months, then as clinically indicated
3. Serum levels: 5-7 days after initiation and dose change, then as clinically indicated
4. As clinically indicated: pregnancy test

DRUG NAME* + Available dosage forms	CLINICAL INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	BOXED WARNING	COMPLICATIONS/ PRECAUTIONS
carbamazepine (CBZ) (Tegretol®) tablets, chewable tablets (some cherry flavor), ER tablets, ER capsules, oral suspension (vanilla, citrus flavor)	**FDA-approved indication:** Seizure disorders **Other clinical uses (**not first-line): - Adjunct for maintenance treatment of bipolar disorder - Schizoaffective disorder - Impulsive aggression	100-1200 Age 6-12: Initial 200 Max 1000 Age ≥13: Initial 400 Max 1200 Therapeutic serum level: 4-12 µg/ml	2-4 x/d	- nausea/vomiting - ataxia - skin rash - dizziness - drowsiness - blurred vision	**Contraindication:** - Use with or within 14 days of discontinuing MAOI - Hypersensitivity to TCA - Bone marrow suppression **Complications**: - Hyponatremia **Precautions**: - Cardiovascular disease - Pregnancy Contents of ER capsules may be sprinkled over food (applesauce); should not be stored for later use	Risk of blood dyscrasias (anemia, agranulocytosis) Severe, sometimes fatal, dermatologic reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis)	**Complications**: - Myelosuppression - Hepatotoxicity - Withdrawal seizures - CNS depression - Drug reaction with eosinophilia and systemic symptoms (DRESS) **Precautions**: - Hepatic impairment
valproic acid (VPA) capsules, oral solution (alcohol free) Divalproex sodium (Depakote®) DR tablets, ER tablets, sprinkle capsules	**FDA-approved indication:** Seizure disorders **Other clinical uses:** - Bipolar disorder - Schizoaffective disorder - Impulsive aggression	125 – 2500 Initial: 15-20mg/kg/d Max: 60mg/kg/d Therapeutic serum levels: 50-125 µg/ml	2-4 x/d	- nausea/vomiting - tremor - weight gain - sedation - headache - skin rash - transient hair loss	**Contraindication:** - Pregnancy **Complications**: - Polycystic ovary syndrome - Thrombocytopenia - Hyperammonemia **Precautions**: - Cardiovascular disease Increase dose by 10-20% if converting from VPA or divalproex sodium DR to divalproex sodium ER Serum levels should be collected 12 hours post-dose for DR tablets, 24 hours post-dose for ER tablets	Hepatotoxicity Teratogenicity (neural tube defects, decreased IQ) Pancreatitis	

** Common brand name is indicated for convenience. No preference is implied*

MOOD STABILIZER – antiseizure agents *(Cont'd)*

DRUG NAME* + Available dosage forms	CLINICAL INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	BOXED WARNING	COMPLICATIONS/ PRECAUTIONS
Lamotrigine (LTG) (Lamictal®) tablets, ER tablets, chewable tablets, oral disintegrating tablets (blackcurrant flavor)	**FDA-approved indication:** Adjunct for seizure disorders **Other clinical uses (**not first-line): - Adjunct for maintenance treatment of bipolar disorder - Schizoaffective disorder	12.5 – 400 Age 6-12: Initial 0.3 mg/kg/d Age ≥13: Initial 25 Adjust dose and titration for concurrent inducers or inhibitors of glucuronidation See package insert for recommended titration schedule	1-2 x/d	- benign rash - headache - nausea/vomiting - abdominal pain - diarrhea - tremor - somnolence - ataxia - dizziness	Consider baseline and follow-up EKG if pre-existing cardiac condition or cardiac risk factors Concurrent use of VPA increases LTG levels by 50%; adjust LTG dose Concurrent use of agents that induce glucuronidation like CBZ decreases LTG levels; adjust LTG dose	Serious dermatologic reactions including Stevens Johnson syndrome	**Complications**: - Blood dyscrasia - Drug reaction with eosinophilia and systemic symptoms (DRESS) - Aseptic meningitis - Withdrawal seizures **Precautions**: - Risk of arrhythmias with structural or functional cardiac condition -

** Common brand name is indicated for convenience. No preference is implied*

ANXIOLYTICS

A. Clinical Indications For Use:

1. short term: relief of anxiety & some sleep disorders
2. acute alcohol withdrawal
3. older adolescents: anxiety, tension, muscle relaxation, sleep disorders
4. younger children: pavor nocturnis, somnambulism

B. Frequency of Dose Change:

1. acute care: daily or with each dose
2. long-term Rx: adjust every 4 days

C. Concomitant Medication Use:

1. potentiated by: phenothiazines, opiates, barbiturates, MAOI's, TCA's, cimetidine
2. potentiate: hypnotics, sedatives, alcohol
3. half-life extended by: renal disease, hepatic disease, oral contraceptives, cimetidine, obesity

D. Complications & Side Effects:

1. CNS depression: fatigue, drowsiness, ataxia, confusion, respiratory depression, death
2. paradoxical: dyscontrol, disinhibition, excitation, ↑ anxiety, ↑ aggression, rage reaction, hallucinations, insomnia, nightmares

E. Cautions/Contraindications:

1. substance abuse or dependency
2. pregnancy

F. Medical Work-up:

1. physical exam (incl. ht, wt, BP, P)

G. Medical Follow-up:

2. if clinically indicated

DRUG (Common brand name is indicated for convenience. No preference is implied.)	MAIN INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	CONTRAINDICATIONS
clonazepam (Klonopin®) *	see class	0.125 - 3	1-2 x/d	see class	see class
alprazolam (Xanax®) **	see class	0.25 - 4	3-4 x/d	see class & increased risk of rebound and withdrawal reactions	see class
lorazepam (Ativan®) **	severe adjustment d/o agitation, anxiety	0.25 - 6	3-4 x/d	see class & increased risk of rebound and withdrawal reactions	see class
buspirone (Buspar®)	anxiety, aggression	2.5 - 90	3-4 x/d		

* long-acting

** short-acting

COMPLEMENTARY/ALTERNATIVE SUPPLEMENTS

DRUG (Common brand name is indicated for convenience. No preference is implied.)	MAIN INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	CAUTIONS/ CONTRAINDICATIONS
melatonin	insomnia	1 - 10	bedtime	dizziness, headaches, intense dreams, abdominal pain	other sedating agents poorly controlled seizures

BETA-ADRENERGIC BLOCKERS

DRUG (Common brand name is indicated for convenience. No preference is implied.)	MAIN INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	CAUTIONS/ CONTRAINDICATIONS
propranolol (Inderal®)	aggression anxiety PTSD	10 – 40	1-4 x/d	hypotension bradycardia depression	bronchospasm disease, cardiovascular disease, diabetes, MAOI, hypothyroidism

OPIOID BLOCKERS

DRUG (Common brand name is indicated for convenience. No preference is implied.)	MAIN INDICATIONS	DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	CAUTIONS/ CONTRAINDICATIONS
naltrexone	self-injurious behavior in IDD & autism	25 – 50	1 x/d 1-2x/d	nausea, headache sedation	liver dysfunction, concurrent opioids

PHARMACOTHERAPY FOR C0-OCCURRING SUBSTANCE USE DISORDERS*

DRUG NAME (Common brand name is indicated for convenience. No preference is implied.)	CLINICAL INDICATIONS	MAX DAILY DOSE	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
naltrexone (oral)	alcohol use disorder	25 – 50	1x/d	nausea, headache, sedation, elevated liver enzymes	may also be administered IM, though data supporting use in adolescents for AUD is mostly oral form	confirm opioid free x7-10 d liver dysfunction, obesity, concurrent opioids (precipitates withdrawal)
N-acetylcysteine (NAC)	cannabis use disorder	2400 (1200 bid)	2x/d	abdominal discomfort, nausea	currently available OTC	no contraindications for oral form
nicotine transdermal patch (Nicoderm CQ®)	tobacco use disorder**	7, 14, 21 >15 cigs/d start 21 < 15 cigs/d start 14	1x/d 24-hour patch	skin irritation, sleep disturbance (remove at night if sleep disturbance occurs)	available OTC (U21 requires prescription) start initial dose x6wks, then step down to lower strength patch q 2 wks	only contraindication is hypersensitivity to nicotine or other ingredients; disease related cautions include CV disease, diabetes, hyperthyroidism, though NRT safer than tobacco use
nicotine gum, lozenge*** (Nicorette®)	tobacco use disorder**	48 (2 mg dose) 96 (4 mg dose)	q 1-2 hrs **prn** x6wks, then: q 2-4 hrs **prn** x3wks, then: q4-8 hrs **prn** x3wks	gum: jaw soreness, mouth irritation, indigestion, nausea, hiccups lozenge: oral irritation, nausea, hiccups	gum: teach “chew and park” method: chew until tingle, then park btn cheek/gum; repeat q1 min lozenge: allow lozenge to slowly dissolve; do not chew or swallow Use >9 pieces/day during initial 6wk	same as patch
bupropion ER (Wellbutrin SR®)	tobacco use disorder**	300 (150 bid)	2x/d	agitation, headache, insomnia, ↑ seizure risk	take early in day to prevent insomnia; lower doses generally less effective	elevated seizure risk (e.g. eating disorder, other Rx)

*Clinicians are encouraged to utilize consultation resources based on their clinical comfort and experience. Always prescribe in combination with behavioral interventions. Limited data for nearly all medication options, and generally reserve for older adolescents and/or in cases of moderate-severe substance use disorders.

**No study has been conducted to assess electronic nicotine delivery systems (ENDS) as a smoking cessation tool in youth; unlike therapies listed here, ENDS have high abuse potential

***Scant evidence for gum and lozenge in U18, though most effective nicotine replacement therapy (NRT) in adults is combination (i.e. patch + gum or patch + lozenge)

PHARMACOTHERAPY FOR CO-OCCURRING SUBSTANCE USE DISORDERS *(Cont'd)**

DRUG NAME (Common brand name is indicated for convenience. No preference is implied.)	CLINICAL INDICATIONS	MAX DAILY DOSE (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
varenicline (Chantix®)	tobacco use disorder**	2 (1 bid)	start 0.5 mg qd x 3 days, then 0.5 mg bid x4 days; then 1 mg bid	drowsiness, seizures	generally 12-wk course, which may be repeated x1	renal dz, cardiovascular dz, seizures early concern for suicidality and neuropsychiatric side effects were unfounded in adults and also not evident in youth studies (*N* > 500)
buprenorphine-naloxone**** (Suboxone®) sublingual tablet, sublingual film	opioid withdrawal syndrome (detox) opioid use disorder (maintenance)	24 (2mg/0.5mg BUP/NAL Ratio)	1-2x/d	headache, insomnia, nausea, constipation, depression, withdrawal sx (either precipitated or if abrupt D/C)	extant data suggests buprenorphine is more effective than clonidine longer detox schedules recommended (e.g. 56-day superior to 28-day); maintenance may have best outcomes	hepatic impairment Submit notice of intent to SAMHSA to begin prescribing: buprenorphine.samhsa.gov
XR-naltrexone (Vivitrol®)	opioid use disorder	n/a	380 mg IM q 4wk	sedation; injection site reactions, headache precipitated withdrawal if opioid dependent	confirm opioid free x7-10 days: use history, urine drug screen and/or oral naltrexone challenge (or SC naloxone challenge)	concurrent opioids (precipitated withdrawal) oral form NOT recommended for OUD
naloxone (Narcan Nasal®)	opioid overdose	1-2 spray: 4mg (intranasal)	repeat dose if not effective after 3 min	precipitated withdrawal	CA law: offer naloxone to any patient at increased risk of opioid overdose at every encounter dispensed in 2-pack with single dose in each	Call 911 upon administration due to short half-life of naloxone

*Clinicians are encouraged to utilize consultation resources based on their clinical comfort and experience. Always prescribe in combination with behavioral interventions. Limited data for nearly all medication options, and generally reserve for older adolescents and/or in cases of moderate-severe substance use disorders.

**No study has been conducted to assess electronic nicotine delivery systems (ENDS) as a smoking cessation tool in youth; unlike therapies listed here, ENDS have high abuse potential

***Scant evidence for gum and lozenge in U18, though most effective nicotine replacement therapy (NRT) in adults is combination (i.e. patch + gum or patch + lozenge)

****FDA-Approved for age 16+: the ONLY medication for addiction treatment that is FDA-approved in adolescents

APPENDIX

PHARMACOKINETIC DRUG INTERACTIONS – CYTOCHROME P450 ENZYME METABOLIZING SYSTEM*

- Substrate: a psychotropic drug that is metabolized by a P450 CYP isoenzyme
- Inhibitor: coadministration of this drug and any substrate in isoenzyme (3A4, 2D6, 1A2) category would result in ↑ substrate levels
- Inducer: coadministration of this drug and any substrate in isoenzyme (3A4, 2D6, 1A2) category would result in ↓ substrate levels

3A4			2D6			1A2		
Substrate	**Inhibitor**	**Inducer**	**Substrate**	**Inhibitor**	**Inducer**	**Substrate**	**Inhibitor**	**Inducer**
alprazolam aripiprazole carbamazepine clonazepam eszopiclone guanfacine lurasidone nefazodone olanzapine pimozide quetiapine ritonavir sertraline trazodone zaleplon ziprasidone zolpidem	fluoxetine fluvoxamine *grapefruit juice* macrolide nefazodone ritonavir	phenobarbital phenytoin rifampin ritonavir *smoking* St. John's wort oxcarbazepine carbamazepine	aripiprazole atomoxetine clozapine dextroamphetamine duloxetine fluphenazine haloperidol mixed amphetamine salts pimozide risperidone TCA trazodone venlafaxine	bupropion cimetidine duloxetine fluoxetine haloperidol paroxetine ritonavir sertraline TCA	carbamazepine phenobarbital phenytoin rifampin ritonavir	amitriptyline caffeine clomipramine clozapine desipramine diazepam haloperidol imipramine	cimetidine ciprofloxacin duloxetine fluoxetine fluvoxamine *grapefruit juice* isoniazid levofloxacin sertraline	phenobarbital phenytoin rifampin ritonavir *smoking*

Other Common Mood Stabilizer Pharmacokinetic Drug interactions		
Interacting drugs	**Mechanism**	**Recommendation**
lamotrigine & valproate	valproate inhibits glucuronidation	Give ½ lamotrigine dose: monitor more closely for rash.
valproate & aspirin	aspirin ↑ free valproate levels	Give acetaminophen instead of aspirin.
lithium & NSAID	NSAID ↓ clearance of lithium	Give acetaminophen instead of NSAID.

* Partial List

INDEX

Suggested References

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(periodical)

American Journal of Psychiatry: Journal of the American Psychiatric Association (periodical)

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Baltimore, MD, William & Wilkins

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Review of Psychotropic Medication Application Forms (PMAFS) for Youth in State Custody
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http://www.dfps.state.tx.us/documents/Child_Protection/pdf/TxFosterCareParameters-September2013.pdf

Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version) – June 2019
The Parameters Workgroup of the Psychiatric Executive Formulary Committee, Health and Specialty Care Division, Texas Health and Human Services Commission. https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/facilities-regulation/psychiatric/psychotropic-medication-utilization-parameters.pdf

TABLE OF CONTENTS

*FIRST GENERATION ANTIPSYCHOTICS

A. Warnings for Concomitant Medication Use:

1. Drugs that lower plasma level: carbamazepine (CBZ), phenytoin (PHT), phenobarbital (PB), smoking
2. Drugs that increase plasma level: fluoxetine, fluvoxamine, paroxetine, macrolide antibiotic, cimetidine
3. Avoid >1 antipsychotic at a time

B. Medical Work-up (Baseline):

1. Physical exam (including height, weight, BMI, BP, pulse, dyskinesia)
2. Lab: fasting blood glucose, Hgb A1c, fasting lipid panel, liver enzymes, CBC + differential, UA, BUN, creatinine
3. Check for abnormal, involuntary movements
4. EKG if at high risk for QTc prolongation

C. Medical Follow-up:

1. Each visit: Abnormal movements, signs/symptoms of hyperprolactinemia, physical exam
2. 2 wks after every dose titration up: Abnormal movements
3. At least every 3 months: AIMS
4. Week 8, week 12 then annually: BMI
5. Week 12 then annually: fasting serum glucose, Hgb A1c, fasting lipid panel, BP, and pulse
6. Annual: Vision screen
7. If clinically indicated: CBC + differential, pregnancy test

Relative risk of adverse side effects, from highest to lowest:	• *EPS:*	haloperidol = fluphenazine > pimozide > perphenazine > chlorpromazine
	• *Hyperprolactinemia:*	haloperidol = fluphenazine > pimozide > perphenazine > chlorpromazine
	• *QTc prolongation:*	pimozide = chlorpromazine > haloperidol = fluphenazine = perphenazine
	• *Sedation:*	chlorpromazine > perphenazine > pimozide = haloperidol = fluphenazine
	• *Orthostatic hypotension:*	chlorpromazine > perphenazine > haloperidol = fluphenazine = pimozide
	• *Diabetes/hyperlipidemia/ weight gain:*	chlorpromazine > haloperidol = perphenazine = fluphenazine = pimozide

DRUG**	CLINICAL INDICATIONS	DOSE^ (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
chlorpromazine (Thorazine®) tablet (can be crushed but with caution for dermatitis), IM injection	Psychosis Not first line in severe behavioral problems d/o with aggression	10 - 800 Max for < 5 y/o: 40 Max for 5-12 y/o: 75	1-6 x/d	- EPS - Sedation - Cognitive dulling - Hypotension - Weight gain - Hyperprolactinemia^^ - Photosensitivity (phenothiazines)	**Contraindications:** Hypersensitivity to sulfites for injection Caution in patients with liver disease Caution in patients with asthma for injection Avoid use of anticholinergics Higher risk of sedation, hypotension	Complications: - Tardive dyskinesia - NMS Precautions: - Blood dyscrasias - Orthostatic hypotension - EKG changes - EEG changes, seizures - Ocular changes - Hyperprolactinemia - Anticholinergic effects - QTc prolongation - Torsades de pointes - Liver disease - Respiratory distress - Pregnancy - Breast feeding
haloperidol (Haldol®) tablet, oral solution, IM injection	Psychosis Tourette Disorder Not first line in severe behavior problems d/o with aggression	0.5 - 15 Max for 3-12 y/o: 0.15mg/kg/day or 6mg/day, whichever is less	2-3 x/d		Higher risk of EPS, hyperprolactinemia	
perphenazine (Trilafon®) tablet	Psychosis	2 - 64	2-4 x		Limited evidence on efficacy and safety for use in age 12 years and younger Use with caution in patients with liver disease Monitor liver function if clinically indicated	
fluphenazine (Prolixin®) tablet, oral solution/elixir, IM injection	Psychosis	1 - 20	2-3 x/d		Limited evidence on efficacy and safety for use in age < 18 Monitor liver enzymes if clinically indicated	

DRUG**	CLINICAL INDICATIONS	DOSE^ (mg/d)	DOSAGE SCHEDULE	ADVERSE EFFECTS	SPECIAL CONSIDERATIONS	COMPLICATIONS/ PRECAUTIONS
pimozide (Orap®) tablet	Tourette's Disorder	1-10 Max for 7-12 y/o: 6mg/day or 0.2 mg/kg/day, whichever is less Max for ≥ 12 y/o: 10mg/day or 0.2 mg/kg/day, whichever is less	1-2 x/d	- Sedation - Cognitive dulling - Hypotension - Weight gain - Hyperprolactinemia^^ - Photosensitivity (phenothiazines)	**Contraindications:** Use of agents that cause tics (methylphenidate, amphetamines), congenital long QT syndrome, history of arrhythmia, hypokalemia, hypomagnesemia, use of other drugs that increase QTc interval, use of fluvoxamine, propranolol, pindolol, fluoxetine, paroxetine (strong CYP2D6 inhibitors), use of strong CYP3A4 inhibitors Monitor: EKG at baseline and each dose increase, liver enzymes at baseline and every 3 months Avoid doses >0.5 mg/kg/day in poor CYP2D6 metabolizers Conduction delays with elevated liver enzymes	Complications: - EPS - Tardive dyskinesia - NMS Precautions: - Blood dyscrasias - Orthostatic hypotension - EKG changes - EEG changes, seizures - Ocular changes - Hyperprolactinemia - Anticholinergic effects - QTc prolongation - Torsades de pointes - Liver disease - Respiratory distress - Pregnancy - Breast feeding

Not included/recommended due to insufficient evidence in youth: **loxapine (Loxitane®), thiothixene (Navane®), perphenazine (Trilafon®)**

* *Not indicated for insomnia.*

** *Common brand name is indicated for convenience. No preference is implied.*

^ *Maximum doses based on literature.*

^^ *More so than novel antipsychotics.*

EPS *Extrapyramidal Symptoms*

TD *Tardive Dyskinesia*

NMS *Neuroleptic Malignant Syndrome*

DRESS *Drug Reaction with Eosinophilia and Systemic Symptoms*

AIMS *Abnormal Involuntary Movement Scale*

Appendix C

Challenges in Diagnosis and Prescribing of Psychotropic Medications

Introduction:

This appendix describes common challenges that occur in psychiatric diagnosis and prescribing for foster youth. The intended audience is JV-220 reviewers, clinicians who conduct peer reviews for quality management purposes, and quality management staff. It can also be a guide for prescribing clinicians who are requesting JV-220 authorization. Additionally, clinicians can use this as a reminder of what practices should be avoided and when consultation or additional support should be requested. Recommendations are provided to assist in responding to the identified challenges.

Common Challenges and Recommendations in Psychotropic Medication Use:

Category	Challenge	Recommendation
Diagnostic clarity	Ongoing use of rule out diagnoses This is the situation where there is a list of possible diagnoses which are never ruled out or ruled in. Clarification of diagnosis is expected to occur over time. Example: Rule out Psychosis NOS	There should documented evidence that an ongoing assessment is occurring and the diagnostic formulation is being completed according to the DSM.
Diagnostic clarity	Multiple diagnoses from several DSM categories. Diagnoses may be proposed from several DSM categories. Each diagnosis may individually be supported by the evaluation and the proposed medication regimen may make sense for each single diagnosis, however, taken together the medications seem to be at cross purposes of each other. Example: Bipolar I Disorder, Attention Deficit Hyperactivity Disorder; Obsessive Compulsive Disorder with a medication regimen	The diagnostic formulation should attempt to address all symptoms with the least number of diagnoses and medications. Medications which exacerbate concurrent illnesses should be avoided.

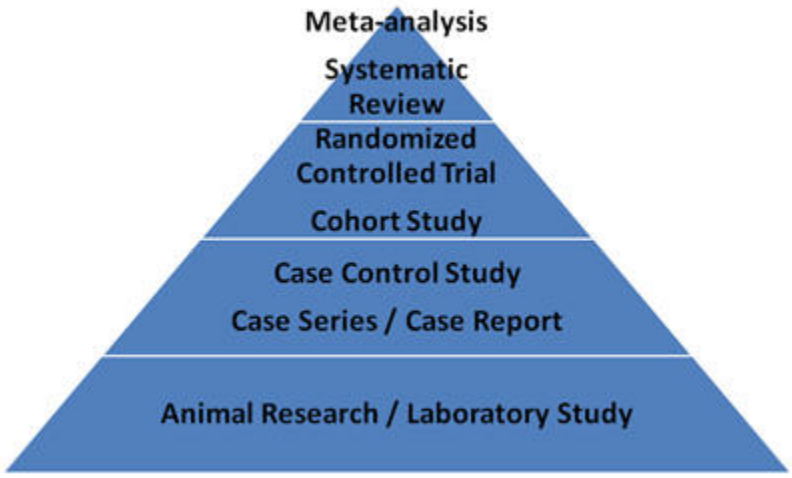
Category	Challenge	Recommendation
	of risperidone, methylphenidate, and sertraline.	
Diagnosis substantiation	Usage of psychiatric terminology over specific description. A psychiatric assessment may heavily rely on impersonal psychological/ medical descriptions of youth, which may or may not support a diagnosis. The use of non-specific symptom terminology does not allow other practitioners to understand the nature or extent of observed symptoms. Example: mood instability	The assessment and diagnostic formulation should employ clear descriptions of behaviors and thoughts rather than non-specific symptom labels.
New medication trials	Initiation of treatment with more than one medication. It can be challenging to determine tolerability or efficacy when multiple medications are started at the same time. This often leads to a scenario where it is unknown why improvement was or was not seen. Example: new start of citalopram **and** bupropion	Start with one medication and add or switch only after a target dose and duration has been achieved.
Polypharmacy	Medications which are ineffective or partially effective are not discontinued. The result of this practice is often an ever increasing number of psychiatric medications with unknown benefits.	The effectiveness of medications should be reviewed on an ongoing basis. Ineffective or partially effective medications should be discontinued in preference of monotherapy whenever possible.
Polypharmacy	Adding or changing two or more medications simultaneously. Similar to starting more than one medication at a time, making multiple medication changes	Only one substitution, addition, or dose change should occur at a time. This may be permissible in unusual circumstances with adequate justification.

Category	Challenge	Recommendation
	concurrently makes it difficult to determine cause and effect.	
Polypharmacy	Indefinite cross titration This situation occurs when one medication is being changed to another via cross titration. However the patients symptoms appear to stabilize during the cross titration and both medications are continued indefinitely.	A full cross over to the new medication should be completed. This should generally be accomplished within 2-3 months.
(stealth polypharmacy)	Over-utilization of as needed medications Medications are initiated as "as needed basis", but end up being used daily (scheduled medications).	Consistent daily use of "as needed" medications needs to be transferred to a maintenance schedule if appropriate, or a changed to a medication targeting the underlying disorder.
Indications for the prescription	Medications prescribed for agitation Agitation is a vague, non-specific descriptor and is not informative in medication selection. Was the child yelling because they were angry? Throwing chairs? It is far too broad of an indication for medication.	Any use of the term "agitation" should require description of specific behaviors and a review of the diagnostic formulation. The underlying disorder should be the primary target for any intervention. If an underlying disorder is absent then psychosocial stressors must be addressed.
Indications for the prescription	Medications are employed in situations not supported by the literature. In some situations, medications are used for symptoms of lower severity and in the absence of a diagnosed disorder. In these cases the efficacy often has not been established and there exists the possibility of over-pathologizing patients and discounting the psychosocial stressors that they are experiencing.	The treatment plan should attempt to alleviate symptoms/ behaviors using behavioral interventions first and foremost. Medications should be reserved for the treatment of disorders and not individual symptoms.

Category	Challenge	Recommendation
	Example: Use of risperidone or aripiprazole for ANY signs of irritability in the absence of Autism.	
Indications for the prescription	Off-label use of medication Roughly 21% of medications across all specialties of medicine are used off-label.[1] However, in some situations, medications are proposed for unorthodox uses or primarily for their side effects, without more conventional medications being utilized first. Alternatively, medications may be used off-label with very little evidence available to support their use.	Any off-label use of medication should have some evidence available to support its use published in peer reviewed literature (see Figure 1). In addition, deviations from general practice guidelines should be adequately supported/ justified.

1. Radley, D.C., S.N. Finkelstein, and R.S. Stafford, *Off-label prescribing among office-based physicians.* Arch Intern Med, 2006. **166**(9): p. 1021-6.

Figure 1. Hierarchy of Evidence for Clinical Questions



Courtesy of UNC Health Sciences Library

Appendix D

Algorithm (decision tree) for the Prescribing of Psychotropic Medications

Basic Principles:

These *Guidelines* are grounded in the following principles and values:

- Safety[i]: Child safety and health are paramount in our work, and children are, first and foremost, protected from abuse and neglect.

- Permanency: Children do best when they have strong families, preferably their own. When that is not possible, a stable, long-term placement with a relative, non-related extended family member, tribal family, foster family, or adoptive family who can meet their physical, emotional, and therapeutic needs is preferred.

- Well-Being: The State and its counties are committed to offering relevant services to children and families to meet their identified needs, build on their strengths, and promote children's development, education, physical and mental health, and general well-being.

    - Most families have the capacity to change with the support of individualized service responses.

    - Children should be placed in the least restrictive setting at which they can be safely treated. Whenever possible, this setting should be within their own community.

- Government cannot do the job alone: Real partnerships with people and agencies involved in a child's life–for example, families, tribes, medical providers, teachers, child care providers, community partners and mentors, including informal and formal mentors, community spiritual and clergy –are essential to ensure child safety, permanency, and well-being, and to build strong families.

- Child centered care: Care should be provided in a manner sensitive to the child's strengths and needs. When developmentally appropriate, children and adolescents should be a part of their health care planning, as described in the Core Practice Model developed in response to the Katie A. lawsuit.

- Continuity of care for children and youth is important: Consistent with the Core Practice Model, these *Guidelines* strive to strengthen coordination across systems of care to minimize the number of unnecessary transitions for children and youth and to support transitions that are necessary when coming into care, during care, and transitioning to permanency.
    - These *Guidelines* are consistent with, and support the goals of, Continuum of Care Reform: The treatment needs of children and youth are best met when services are provided at the lowest level of care at which the client can be safely treated.
    - Critical to the success of these Guidelines and inter-related State initiatives is access to providers who have the capacity and specialized competencies to serve our children and youth, as well as access to these providers within timeframes that meet the needs of children and youth.
- Quality: The State and its counties expect our children to receive high quality healthcare, inclusive of physical, emotional/behavioral, and dental health.
- Integration: These inclusive health care needs of a child/youth are expected to be integrated into a health care services plan that provides integrated, coordinated services that are individualized and tailored to the strengths and needs of each child and their family.
- Collaboration: The State and its counties recognize the importance of collaboration with treatment providers, particularly prescribing providers, to ensure the success of these *Guidelines* and psychotropic medication management reform for children and youth in out of home care served by child welfare and/or probation.
- Limitations: Psychotropic medication is never the sole intervention but should be part of an overall treatment strategy ([ii]T-May 2010). Medication also carries the risk of adverse (side) effects, so careful monitoring by the prescriber is essential.

Below is an algorithm (decision tree) designed to assist the prescriber in maintaining compliance with State and county regulations and guidelines pertaining to the prescribing of psychotropic medications for children and youth in foster care.

Before prescribing, have the following concerns been considered:

- ☐ Might the existing treatment be exacerbating the child's behavior?
- ☐ Weigh the potential benefits and risks of psychotropic medication use against the risks of untreated illness.
- ☐ Caution is recommended in prescribing psychotropic medications to children and adolescents especially those for which long term consequences are incompletely understood.
- ☐ Are there evidence-supported non-pharmacological treatments appropriate for this child/youth available in the community?
- ☐ If non-pharmacological treatments been offered by an appropriately trained provider? If so, was the length of treatment adequate to evaluate treatment effectiveness, as evidenced by written documentation provided by the therapist?
- ☐ If there are no evidence-supported psychotherapeutic treatments appropriate for this child/youth available in the community, could other mental health interventions be tried?
- ☐ Are there environmental factors, e.g., in the placement or school setting, that could or should be addressed first?
- ☐ A consult with a psychiatric specialist is indicated if there is a question of neurological or medical conditions contributing to the child's symptoms or if medication is a possible component of treatment.
- ☐ Medication adherence is an important component of the treatment plan. As part of the informed consent and assent process, the prescriber discusses medication adherence with the youth and family, including the physical and behavioral consequences of abrupt withdrawal. Adverse effects should routinely be discussed as part of informed consent and assent.

- ☐ If there is concurrent substance abuse and prescription of psychotropic medication is being considered, the prescriber considers need for concurrent dual diagnosis (mental health and substance abuse) treatment to ensure concerns in both domains are addressed. Medications should be considered with care during events or situations which may be stressful or traumatic for a youth, such as the initial removal from the home, or a change of placement.

- ☐ When indicated, psychotropic medications are to be prescribed as part of a documented comprehensive treatment plan and not as the sole intervention. They are not prescribed in lieu of instituting available non-pharmacological treatments that are evidence-supported and that target the individual child's needs.

When prescribing, consider the following:

- ☐ Preference is given to FDA approved medications, or medications clinically indicated for off-label use for a child's age group and diagnosis before other medications are tried.

- ☐ Is there a generic equivalent of medication available?

- ☐ Medications that have more data regarding safety and efficacy for children are preferred over newly FDA-approved medications.

- ☐ Medication dosages should be kept within FDA guidelines for children when these are available. Any deviation from FDA guidelines is to be documented with the underlying rationale in the child's treatment records.

- ☐ Treatment with a single medication for a single symptom or disorder should be tried before treatment with multiple medications is considered.

- ☐ The use of two or more medications for the same symptom or disorder requires specific documentation from the prescribing clinician in the child's health record.

- ☐ In most circumstances, only one medication should be changed at one time.

- ☐ Medications should be initiated at a low dose and increase gradually only if there is a lack of response to medication. The clinical wisdom, "start low and go slow" is particularly relevant when treating children in order to minimize side effects and to observe for therapeutic effects.

- ☐ The decision to treat a child with more than one medication from the same class should be supported by written documentation in the child's health record from the prescribing clinician and may warrant a second review by a Child and Adolescent Psychiatrist.
- ☐ A clinician prescribing more than 3 psychotropic medications to one child must justify and document the rationale for doing so in the child's treatment plan and may warrant a second review by a Child and Adolescent Psychiatrist. Multiple psychotropic medications are indicated only when multiple separate diagnoses have been documented.
- ☐ If this is not the first prescription for psychotropic medication for this child, periodic evaluation of treatment efficacy and tolerability should occur, as described above. At each subsequent appointment for medication management, this evaluation includes review of the following:
- ☐ Is there amelioration of symptoms of behavioral dyscontrol or emotional distress as assessed by clinical interview, collateral reports, validated assessment instruments (e.g., Beck Youth Inventories, Trauma Symptom Checklist for Children), and improved psychosocial functioning?
- ☐ Are target symptoms well controlled in at least one of the child's natural environments (excludes group homes and Residential Treatment Centers)?
- ☐ Are the medication dose and duration adequate?
- ☐ Has child/youth (or care environment as a whole) received appropriate evidence-supported psychotherapeutic treatments (if indicated)?
- ☐ Has the child/youth received informal psychosocial supportive interventions that promote development of resilience and learned control?
- ☐ What is the child/youth's perspective regarding the medication? Does the child/youth state that the medication is helpful?
- ☐ Do the observed therapeutic benefits to date outweigh the potential risks?
- ☐ Are there any medication adverse effects that indicate a need for tapering dosage and/or discontinuation?

- ☐ Efforts have been made to adjust medication dose to the minimum at which it remains effective and side effects are minimized. These efforts, or reasons why adjustments could not be considered, are documented in the youth's Treatment Plan and have been discussed with the youth and family.

- ☐ Periodic attempts at taking the child off medication have been tried or were determined to not be appropriate at this time. Efforts to discontinue the medication(s), or the rationale for continuing the medication, are documented in the child's Treatment Plan.

- ☐ The child/adolescent should be monitored for adverse effects, such as movement disorders, extreme weight gain or loss, and documentation should be present in the child's medical/psychiatric record.

- ☐ If adverse effects occur, tapering off the medication may be indicated, and identification of another clinically appropriate intervention is encouraged. These side (adverse) effects and efforts to taper and identify another clinically appropriate intervention are documented in the youth's Treatment Plan.

- ☐ The youth and family are consulted in discussions regarding tapering or discontinuing medication and identification of potential alternatives.

- ☐ Caution and pause should be used before treating side effects with the addition of medication. If used, the rationale is documented in the youth's Treatment Plan. The rationale also has been discussed with the youth and family; this discussion also is documented in the youth's Treatment Plan.

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[i] *Crystal SC, Olfson M, Huang C, et al. Broadened use of atypical antipsychotic drugs: safety, effectiveness, and policy challenges. Health Affairs. 2009; 28:770-781*.

[ii] *T-MAY Treatment of Maladaptive Aggression in Youth, 2010*.