

Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version)

Developed by:

The Parameters Workgroup of the Psychiatric Executive Formulary Committee, Health and Specialty Care Division, Texas Health and Human Services Commission

Review and Input Provided by:

The University of Texas at Austin College of Pharmacy
The UT System Medical Schools
Texas A&M Health Science Center
Texas Tech University Health Sciences Center

June 2019

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Introduction and General Principles

The Psychotropic Medication Utilization Parameters were initially developed in 2004 to provide evidence-informed guidance on the use of psychotropic medication with children and youth and suggest parameters for utilization review. While the most recent versions have focused primarily on children within the Texas foster care system, this sixth iteration of the Psychotropic Medication Utilization Parameters has been refocused to address the treatment of all children and adolescents served by the public behavioral health system in Texas. It has long been recognized that the Parameters are based upon sound psychiatric principles and scientific evidence that apply to all children and adolescents who are treated with these medications. Additionally, the development of the Parameters has returned to the public behavioral health section that sponsored the first edition in 2004. Currently the professionals responsible for the sixth version constitute a Workgroup of the Psychiatric Executive Formulary Committee (PEFC) of the Health and Specialty Division of the Texas Health and Human Services Commission. The PEFC addresses the formulary and prescribing parameters that are used in the Texas state mental hospitals, state supported living centers, local mental health authorities, local intellectual disability health authorities, and their contractors.

The use of psychotropic medications in children and adolescents is an issue confronting parents, other caregivers, and health care professionals across the United States. This population has multiple and complex care needs relating to rapid developmental changes, incomplete brain maturation, diagnostic uncertainty, incomplete long-term evidence base for most medication classes, impact of ecological systems such as family and school, and issues of self-determination. Additionally, children and youth, especially those in foster care for whom the Parameters were originally developed, may have treatment complexity related to emotional or psychological stress. They may have experienced abusive, neglectful, serial or chaotic caretaking environments. Birth family history may not be available. These traumatized children often present with a fluidity of different symptoms over time reflective of past traumatic events that may mimic or underlie many psychiatric disorders and result in difficulties with attachment, mood regulation, behavioral control, and other areas of functioning. In view of these considerations, the American Academy of Child and Adolescent Psychiatry (AACAP) emphasizes the importance of holistic and collaborative mental health treatment, recommending prescribers of psychotropic medication in child-serving systems utilize a biopsychosocial perspective guided by trauma-informed and system of care principles. A trauma-informed approach involves understanding the prevalence and impact of trauma, recognizing trauma signs and symptoms, responding with trauma-sensitive procedures and practices, and endeavoring to minimize re-traumatization. The system of care framework includes providing effective services that are family-driven and youthguided, home and community-based, strengths-based and individualized and culturally and linguistically appropriate.

Additionally, it is important that a comprehensive evaluation be performed before beginning treatment for a mental or behavioral disorder. Except in the case of an emergency, a child should receive a thorough health history, psychosocial assessment, mental status exam, and physical exam before prescribing a psychotropic medication. The physical assessment should be

performed by a physician or another healthcare professional qualified to perform such an assessment. It is recognized that in some emergency situations, it may be in the best interest of the child to prescribe psychotropic medications before a physical exam can be performed. In these situations, a thorough health history should be performed to assess for significant medical disorders and past response to medications, and a physical evaluation should be performed as soon as possible. A thorough psychosocial assessment should be performed by an appropriately qualified mental health clinician (licensed masters or doctoral level), a psychiatrist/ child psychiatrist, or a primary care physician with experience in providing mental health care to children and youth. The child's symptoms and functioning should be assessed across multiple domains and multiple informants when possible, and the assessment should be developmentally age appropriate. It is very important that information about the child's history, including history of trauma and current functioning be made available to the treating physician in a timely manner, either through an adult who is well-informed about the child or through a comprehensive medical record. It is critical to meet the individual needs of patients and their families in a culturally competent manner. This requirement indicates a need to address communication issues as well as differences in perspectives on issues such as behavior and mental functioning. Interpretation of clinical symptoms and decisions concerning treatment should, whenever possible, be informed by the child's current level of biopsychosocial developmental as well as history of trauma, neglect or abuse and the timing of these stressors. In general, optimal outcomes are achieved with well-coordinated teambased care with members of different professions (e.g., child psychiatrist, child psychologist, social worker, primary care physician, etc.) each contributing their particular expertise to the treatment plan and follow- up. Note well: At present there are no biomarkers to assist with the diagnosis of mental disorders, and imaging (e.g., MRI) and other tests (e.g., EEG) are not generally helpful in making a clinical diagnosis of a mental disorder. Consequently, the diagnosis is based on a comprehensive clinical assessment.

Prescribers should be mindful of the important role of nonpharmacological, psychosocial treatments in remediating behavioral and emotional disturbances among youth. In many instances, especially with milder presentations, it is prudent to undertake psychotherapy or environmental changes before beginning pharmacotherapy. In other situations, pharmacotherapy may help attenuate symptoms and distress so that psychosocial treatment may be successfully implemented. For instance, youth with more severe anxieties may benefit from anxiolytic medications to enable their participation in evidence-based treatments that involve exposure and skills development. Similarly, children with highly disruptive or aggressive conduct with comorbid ADHD may first need pharmacotherapy that reduces ADHD-related impulsivity before behavioral therapies can gain traction. Therefore, whenever possible and appropriate, psychotherapy should generally begin before or concurrent with prescription of a psychotropic medication. Equally important, the role of the health care provider and the health care environment's potential to exacerbate a child's symptoms, given their respective trauma history, should be considered and minimized through trauma-informed approaches to care. Patient and caregiver education should be provided about the condition to be treated, treatment options (non- pharmacological and pharmacological), treatment

expectations, and potential side effects that may occur during the prescription of psychotropic medications.

It is recognized that many psychotropic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. The FDA has a statutory mandate to ensure that approved product labeling accurately reflects pharmaceutical company sponsored research on safety and efficacy for the indications listed. The FDA does not regulate physician and other health provider practice. In fact, the FDA has stated that it does "not limit the way a practitioner may prescribe an approved drug." Studies and expert clinical experience often support the use of a medication for an "off-label" use. This practice is particularly relevant in child psychiatry as there is a dearth of FDA-registration trials in youth. Physicians therefore must use the available evidence, expert opinion, their own clinical experience, and exercise their clinical judgment in prescribing what is best for each individual patient. To that end, clear documentation of the physician's rationale in the medical record facilitates continuity of care and minimizes misinterpretation.

Role of Primary Care Providers

Primary care providers play a valuable role in the care of youth with mental disorders. Not only are they the clinicians most likely to initially interact with children who are in distress due to an emotional or psychiatric disorder, but also an inadequate number of child psychiatrists are available to meet children's mental health needs. Primary care clinicians are in an excellent position to perform screenings of children for potential mental disorders, and they can diagnose and treat relatively straightforward situations such as uncomplicated ADHD, anxiety, or depression. Primary care providers should provide advice to youth, including those in foster care, and their care givers about handling feelings and behaviors, recognizing the need for help, making decisions regarding healthy life styles, and the available treatments for childhood mental disorders. As always, consideration should be given regarding the need for referral for counseling, psychotherapy, or behavioral therapy. Primary care providers vary in their training, clinical experience, and confidence to address mental disorders in children. Short courses and intensive skills-oriented seminars may be beneficial in assisting primary care clinicians in caring for children with mental disorders. Active liaisons with child psychiatrists who are available for phone consultation or referral can be beneficial in assisting primary care clinicians to meet the mental health needs of children. For children and youth in foster care, the American Academy of Pediatrics has provided a policy statement ("Health Care Issues for Children and Adolescents in Foster Care and Kinship Care") which can be found at:

http://pediatrics.aappublications.org/con-tent/136/4/e1131

General Principles

A DSM-5 psychiatric diagnosis should be made whenever possible before the prescribing of psychotropic medications. If a diagnosis cannot be reached, rational pharmacology based on specific symptom management may be necessary while additional clinical information is gathered.

Clearly defined target symptoms and treatment goals for the use of psychotropic medications should be identified and documented in the medical record at the time of or before beginning treatment. These target symptoms and treatment goals should be assessed at each clinic visit with the child and caregiver in a culturally and

linguistically appropriate manner. Whenever possible, standardized clinical rating scales (clinician, patient, primary caregiver, teachers, and other care providers) or other measures should be used to quantify the response of the child's target symptoms to treatment and the progress made toward treatment goals. In deciding whether to prescribe a psychotropic medication in a specific child, the clinician should carefully consider potential side effects, including those that are uncommon but potentially severe, and evaluate the overall benefit to risk ratio of pharmacotherapy. Except in the case of an emergency, informed consent should be obtained from the appropriate party(s) and assent from the child or adolescent before beginning psychotropic medication. Informed consent to treatment with psychotropic medication entails diagnosis, expected benefits and risks of treatment, including common side effects, discussion of laboratory findings, and uncommon but potentially severe adverse events. Alternative treatments, the risks associated with no treatment, and the overall potential benefit to risk ratio of treatment should be discussed.

Medication management should be collaborative. Youth, as well as caregivers, should be involved in decision- making about treatment, in accordance with their developmental level. Parents providing informed consent should be engaged, and where applicable, other caregivers, family, and child related agencies should be involved. Whenever possible, trauma-informed, evidence-based psychotherapy, should begin before or concurrent with the prescription of psychotropic medication. Before starting psychopharmacological treatment in preschool-aged children even more emphasis should be placed on treatment with non-psychopharmacological interventions, as this age group has few FDA-approved psychiatric treatments and even less of a clinical research base than older youth. Assessment of parent functioning and mental health needs, in addition to training parents in evidence-based behavior management can also reduce the need for the use of medication. During the prescription of psychotropic medication, the presence or absence of medication side effects should be documented in the child's medical record at each visit. Appropriate monitoring of indices such as height, weight, blood pressure, or laboratory findings should be documented.

Monotherapy regimens for a given disorder or specific target symptoms should usually be tried before polypharmacy regimens. While the goal is to use as few psychotropic medications as can be used to appropriately address the child's clinical status, it is recognized that the presence of psychiatric comorbidities may affect the number of psychotropic medications that are prescribed. When polypharmacy regimens are needed, addition of medications should occur in a systematic orderly process, accompanied by on-going monitoring, evaluation, and documentation. The goal remains to minimize polypharmacy while maximizing therapeutic outcomes. Medications should be initiated at the lower end of the recommended dose range and titrated carefully as needed. Only one medication should be changed at a time, unless a clinically appropriate reason to do otherwise is documented in the medical record. (Note: starting a new medication and beginning the dose taper of a current medication is considered one medication change).

The use of "prn" or as needed prescriptions is discouraged. If they are used, the situation indicating need for the administration of a prn medication should be clearly indicated as well as the maximum dosage in a 24-hour period and in a week. The

frequency of administration should be monitored to assure that these do not become regularly scheduled medications unless clinically indicated. The frequency of clinician follow-up should be appropriate for the severity of the child's condition and adequate to monitor response to treatment, including: symptoms, behavior, function, and potential medication side effects. At a minimum, a child receiving psychotropic medication should be seen by the clinician at least once every ninety days. The potential for emergent suicidality should be carefully evaluated and monitored, particularly in depressed children and adolescents as well as those beginning antidepressant treatment, those having a history of suicidal behavior or deliberate self-harm, and those with a history of anxiety or substance abuse disorders. Youth at risk of suicide should have a written, collaborative safety plan that is regularly monitored. If the prescribing clinician is not a child psychiatrist, referral to or consultation with a child psychiatrist, or a general psychiatrist with significant experience in treating children, should occur if the child's clinical status has not shown meaningful improvement within a timeframe that is appropriate for the child's diagnosis and the medication regimen being used.

Before adding additional psychotropic medications to a regimen, the child should be assessed for adequate medication adherence, appropriateness of medication daily dosage, accuracy of the diagnosis, the occurrence of comorbid disorders (including substance abuse and general medical disorders), and the influence of psychosocial stressors. If a medication has not resulted in improvement in a child's target symptoms (or rating scale score), discontinue that medication rather than adding a second medication to it.

If a medication is being used in a child for a primary target symptom of aggression associated with a DSM-5 non-psychotic diagnosis (e.g., conduct disorder, oppositional defiant disorder, intermittent explosive disorder), and the behavior disturbance has been in remission for six months, then serious consideration should be given to slow tapering and discontinuation of the medication. If the medication is continued in this situation, the necessity for continued treatment should be evaluated and documented in the medical record at a minimum of every six months. The clinician should clearly document care provided in the child's medical record, including history, mental status assessment, physical findings (when relevant), impressions, rationale for medications prescribed, adequate laboratory monitoring specific to the drug(s) prescribed at intervals required specific to the prescribed drug and potential known risks, medication response, presence or absence of side effects, treatment plan, and intended use of prescribed medications.

Use of Psychotropic Medication in Preschool Age Children

The use of psychotropic medication in young children of preschool ages is a practice that is limited by the lack of evidence available for use of these agents in this age group. The Preschool Psychopharmacology Working Group (PPWG) published guidelines (Gleason 2007) summarizing available evidence for use of psychotropic medications in this age group. The PPWG was established in response to the clinical needs of preschoolers being treated with psychopharmacological agents and the absence of systematic practice guidelines for this age group, with its central purpose to attempt to promote an evidence-based, informed, and clinically sound approach when considering medications in preschool-aged children.

The PPWG guidelines emphasize consideration of multiple different factors when deciding on whether to prescribe psychotropic medications to preschool-aged children. Such factors include the assessment and diagnostic methods utilized in evaluating the child for psychiatric symptoms/illness, the current state of knowledge regarding the impact of psychotropic medication use on childhood neurodevelopmental processes, the regulatory and ethical contexts of use of psychotropic medications in small children (including available safety information and FDA status), and the existing evidence base for use of psychotropic medication in preschool aged children. It should be noted here that although the FDA many decades ago approved marketing of chlorpromazine for use in children down to the age of 6 months, this approval was based on clinical practice and not on a rigorous demonstration of efficacy and safety that would be required for approval today. Essentially this use was "grandfathered" in and current prescription for children and adolescents is limited, the evidence base is not current and very thin despite the long history of use in the past.

Very limited information is available regarding the use of antipsychotics in the preschool age population, and no information is available regarding the use of longacting injectable (LAI) antipsychotics in this population. Not having information to describe the effects of antipsychotics on growth and development in preschoolers is of concern. Many antipsychotics produce significant weight gain in children, and this should be of concern in the preschool population. Akathisia may also be an issue in the preschool population. The use of antipsychotics in preschoolers should be limited to the most severe situations, and the goal should be for it to be of short duration. For these reasons, antipsychotic LAIs are not recommended in the preschool population. The publication includes specific guidelines and algorithm schematics developed by the PPWG to help quide treatment decisions for several psychiatric disorders that may present in preschool-aged children, including Attention-Deficit Hyperactivity Disorder, Disruptive Behavioral Disorders, Major Depressive Disorder, Bipolar Disorder, Anxiety Disorders, Post-Traumatic Stress Disorder, Obsessive-Compulsive Disorder, Pervasive Developmental Disorders, and Primary Sleep Disorders. The working group's key points and guidelines are like the general principles regarding the use of psychotropic medication in children already detailed in this paper. However, the working group's algorithms put more emphasis on treating preschool-aged children with non-psycho- pharmacological interventions (for up to 12 weeks) before starting psychopharmacological treatment, to be very cautious in introducing psychopharmacological interventions to rapidly developing preschoolers. The working group also emphasizes the need to assess parent functioning and mental health needs, in addition to training parents in evidence-based behavior management, since parent behavior and functioning can have a large impact on behavior and symptoms in preschool-aged children.

Treatment of Opioid Use Disorders in Adolescents

Unfortunately, the opioid crisis in the US extends into the adolescent population and physicians are being confronted with the need to make recommendations and treatment decisions in this area. Although extensive discussion is beyond the scope of this document, there are 3 available options for Medication Assisted Treatment (MAT) in adolescents: buprenorphine, naltrexone and methadone. A good overview can be found in The ASAM National Practice Guideline for the Use of Medications in the

Treatment of Addiction Involving Opioid Use (2015). This guideline makes the following recommendations which have not changed in the face of more recent albeit scant literature:

- Clinicians should consider treating adolescents who have opioid use disorder using the full range of treatment options, including pharmacotherapy that are available for adults. N.B: Prescription of buprenorphine and/or methadone requires special provider qualifications. Further information may be found at https://www.samhsa.gov/medication-assisted-treatment/treatment.
- 2. Opioid agonists (methadone and buprenorphine) and antagonists (naltrexone) may be considered for treatment of opioid use disorder in adolescents. Age is a consideration in treatment, and Federal laws and US FDA approvals need to be considered for patients under age 18. See 42 CFR 8.12 (e) (2): "Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment."
- Psychosocial treatment is recommended in the treatment of adolescents with opioid use disorder and required under federal law for those receiving methadone.
- 4. Concurrent practices to reduce infection (e.g., sexual risk reduction interventions) are recommended as components of comprehensive treatment for the prevention of sexually transmitted infections and blood-borne viruses.
- 5. Adolescents may benefit from treatment in hospitals or other specialized treatment facilities that provide multidimensional services.

Levels of Warnings Associated with Medication Adverse Effects

Psychotropic medications have the potential for adverse effects. Some adverse effects are time-limited and remit with continued treatment; others require intervention for effective management, and in some situations compel discontinuation of the medication that causes them. Some adverse effects are detected prior to marketing and are included in the FDA approved product labeling provided by the manufacturers. When looking at product labeling, these adverse effects will be listed in the "Warnings and Precautions" section. As well, the "Adverse Reactions" section of the product labeling will outline those adverse effects reported during clinical trials, as well as those discovered during post-marketing evaluation. Many tertiary drug information resources also list common adverse effects and precautions for use with psychotropic medications.

At times, post-marketing evaluation may detect critical adverse effects associated with significant morbidity and mortality. The Food and Drug Administration (FDA) may require manufacturers to revise product labeling to indicate these critical adverse effects. If found to be particularly significant, these effects are demarcated by a box outlining the information at the very beginning of the product labeling, and have, in turn, been named boxed warnings. Boxed warnings are the strongest warning required by the FDA. It is important for clinicians to be familiar with all medication adverse effects, including boxed warnings, to appropriately monitor patients and

minimize the risk of their occurrence. The medication tables include boxed warnings as well as other potential adverse effects. The list of potential adverse effects in the tables should not be considered exhaustive, and the clinician should consult the FDA approved product labeling and other reliable sources for information regarding medication adverse effects.

The FDA has in recent years taken additional measures to try to help patients avoid serious adverse events. New guides called Medication Guides have been developed and are specific to medication and medication classes. Medication Guides advise patients and caregivers regarding possible adverse effects associated with classes of medications and include pre- cautions that they or healthcare providers may take while taking/prescribing certain classes of medications. The FDA requires that Medication Guides be issued with certain prescribed medications and biological products when the Agency determines that certain information is necessary to prevent serious adverse effects, that patient decision- making should be informed by information about a known serious side effect with a product, or when patient adherence to directions for the use of a product are essential to its effectiveness. During the drug distribution process, if a Medication Guide has been developed for a certain class of medications, then one must be provided with every new prescription and refill of that medication.

Copies of the Medication Guides for psychotropic medications can be accessed on the FDA website at: http://www.fda.gov/Drugs/Drugs/DrugSafety/ ucm085729.htm.

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

The following situations indicate a need for review of a patient's clinical care. These parameters do not necessarily indicate that treatment is inappropriate, but they do indicate a need for further review. For a child being prescribed a psychotropic medication, any of the following suggests the need for additional review of a patient's clinical status:

- Absence of a thorough assessment for the DSM-5 diagnosis(es) in the child's medical record.
- Four (4) or more psychotropic medications prescribed concomitantly (side effect medications are not included in this count).
- Prescribing of:
 - ▶ Two (2) or more concomitant stimulants*
 - Two (2) or more concomitant alpha agonists*
 - ▶ Two (2) or more concomitant antidepressants
 - ▶ Two (2) or more concomitant antipsychotics
 - ▶ Three (3) or more concomitant mood stabilizers
 - *The prescription of a long-acting and an immediate-release stimulant or alpha agonist of the same chemical entity does not constitute concomitant prescribing.
- Note: When switching psychotropic medications, overlaps and cross taper should occur in a timely fashion, generally within 4 weeks.
- The prescribed psychotropic medication is not consistent with appropriate care for the patient's diagnosed mental disorder or with documented target

- symptoms usually associated with a therapeutic response to the medication prescribed.
- Psychotropic polypharmacy (2 or more medications) for a given mental disorder is prescribed before utilizing psychotropic monotherapy.
- The psychotropic medication dose exceeds usual recommended doses (literature based maximum dosages in the following tables).
- Psychotropic medications are prescribed for children of very young age, including children receiving the following medications with an age of:
 - ▶ Stimulants: Less than three (3) years of age
 - ▶ Alpha Agonists: Less than four (4) years of age
 - ▶ Antidepressants: Less than four (4) years of age
 - ▶ Mood Stabilizers: Less than four (4) years of age
 - Antipsychotics: Less than five (5) years of age
- Prescribing by a primary care provider who has not documented previous specialty training for a diagnosis other than the following (unless recommended by a psychiatrist consultant):
 - Attention Deficit Hyperactive Disorder (ADHD)
 - Uncomplicated anxiety disorders
 - Uncomplicated depression
 - Antipsychotic medication(s) prescribed continuously without appropriate monitoring of glucose and lipids at least every 6 months.

Usual Recommended Doses

These tables were reviewed and updated by the Parameters Workgroup of the Psychiatric Executive Formulary Committee in 2023. It is available under Resources at Psychiatric Drug Formulary | Texas Health and Human Services,

Special Considerations

It is best to optimize the dose of psychotropic medication and allow an adequate trial (usually 4-8 weeks, depending on medication class) before a switch in psychotropic medication is performed, unless adverse effects prohibit or limit the current treatment.

Titration of Antidepressant Medications

For most antidepressant medications, start at the recommended initial dose and wait approximately one week in between dose increases (as tolerated) until the target dose is achieved. It is recommended to start low and go slow to reduce treatment-emergent anxiety and potential activation. Guidelines suggest weekly contact with the young patient and their parent/caregiver for the first 4 weeks of treatment and bi-weekly thereafter. (NICE 2005; AACAP 2007; FDA) As with other medications treatments for Major Depressive Disorder and anxiety disorders, symptom improvement/response may be delayed until 4 weeks of treatment or longer.

Taper of Antidepressant Medications

<u>For antidepressant treatment duration >4-6 weeks, taper is recommended</u> to avoid withdrawal symptoms (flu-like symptoms, anxiety, irritability, nausea, 'electric shock' sensation, etc.) and to reduce potential for symptom worsening and relapse. The

taper schedule should be tailored depending on patient diagnosis and individual characteristics.

Abrupt discontinuation of antidepressant medications is generally NOT recommended. For significant or severe adverse effects, abrupt discontinuation may be advised; however, withdrawal adverse effects and relapse/symptom exacerbation are possible. A number of strategies for switching or discontinuing antidepressant medications have been studied in adults. A paucity of evidence exists to guide best practice for antidepressant tapering and discontinuation in youth. The following is based on review of available data, clinical experience, and expert consensus.

<u>Tapering to discontinue:</u> Antidepressant taper should occur slowly over at least 4 weeks [Example taper schedule: 10-20-25% dose reduction (from initial dose) each week until discontinuation is complete].

For patients achieving remission on antidepressant medications for a significant duration of time OR if significant withdrawal symptoms/symptom recurrence occur(s) during taper, a longer and slower taper can be considered (up to 12 weeks). Switching between antidepressant classes: Cross-taper should occur over no longer than 4 weeks. Use caution using two antidepressant medications in higher doses to reduce the risk of serotonin syndrome (symptoms include: hyperthermia, hyperreflexia, agitation, tremor, sweating, altered mental status, tachycardia, etc.). An example taper schedule is: 25-50% dose reduction each week of previous antidepressant with titration of new antidepressant starting at 25% of target dose, then increasing over 2-4 weeks to target dose.

<u>Switching between SSRIs:</u> In cases of switching between SSRI medications, a direct switch can be performed (i.e., take the last dose of one SSRI medication one day, and then start an equivalent/therapeutic dose of a different SSRI the next day and discontinue previous SSRI). Taper is also possible, with a taper duration not to exceed approximately 2 weeks.

Individual medication considerations for tapering:

<u>Fluoxetine</u>: Due to the long half-life of fluoxetine (and active metabolite norfluoxetine), if dose is less than 40 mg/day, you may consider taper and discontinuation over 7-14 days [e.g., reduce to 20 mg for 7 days, then 10 mg for 7 days, then stop] depending on individual clinical factors. A longer taper is recommended if withdrawal symptoms occur or if clinical presentation worsens during taper.

<u>Paroxetine:</u> Due to the short half-life of paroxetine, a longer and slower taper may be necessary with a goal of discontinuation to prevent withdrawal and symptom exacerbation.

Titration of Antipsychotic Medications

These tables were reviewed and updated by the Parameters Workgroup of the Psychiatric Executive Formulary Committee in 2023. It is available under Resources at Psychiatric Drug Formulary | Texas Health and Human Services,

Taper of Antipsychotic Medications

Several strategies for switching or discontinuing antipsychotic medications have been studied in adults. A paucity of evidence exists to guide best practice for antipsychotic tapering and discontinuation in youth. The following is based on review of available data, clinical experience, and expert consensus.

In patients with antipsychotic use > 4 weeks, psychotic disorders, patients with a history of repeated relapse, or treatment resistant symptoms, abrupt antipsychotic discontinuation is generally not advised. Withdrawal adverse effects and relapse/symptom exacerbation are possible. For dangerous or severe adverse effects, abrupt discontinuation may be necessary to reduce the risk of potential harm to the patient. Neuroleptic malignant syndrome (NMS) is a life-threatening reaction to antipsychotic medications, which typically presents with high fever, muscle rigidity, confusion, autonomic instability, etc. In the case of neuroleptic malignant syndrome, abrupt discontinuation of the antipsychotic is required, as well as emergency management to reduce body temperature and blood pressure. For patients experiencing less-severe treatment-emergent adverse effects for which discontinuation is desired, a faster taper may also be possible, depending on clinician discretion/judgment.

For antipsychotic treatment duration >4 weeks, taper is recommended to avoid withdrawal symptoms (withdrawal dyskinesia, etc.) and to reduce potential for symptom worsening and destabilization. The taper schedule should be tailored depending on patient diagnosis and individual characteristics, as well as, the goal of medication switch vs. discontinuation. A faster taper may be possible under close monitoring during inpatient hospitalization.

Tapering to discontinue: Antipsychotic taper should occur in increments over at least 3-4 weeks [example taper schedule: 25%-50% dose reduction initially (from initial dose), then reduce by 25% bi-weekly or once a week]. A longer taper is recommended if withdrawal symptoms occur or if clinical presentation worsens during taper, or if the goal of taper is to discontinue after remission of symptoms has occurred for an adequate period depending on the condition being treated. Switching between antipsychotics: If switching antipsychotics, it is generally advisable to cross-taper/titrate agents concurrently over approximately 2 weeks. Judicious dosing of the newly started agent is advised to reduce the potential for extrapyramidal adverse effects. Direct switch between antipsychotics has been studied in adult patients with mixed results. If direct antipsychotic switch is utilized in youth, close monitoring is recommended. Gradual discontinuation/cross-taper may be most appropriate for the majority of patients. In all cases, the period of overlapping antipsychotic administration should be minimized to no longer than 4 weeks. Antipsychotic polypharmacy taper: In patients taking two antipsychotics concurrently for maintenance treatment, you may consider slowly tapering one antipsychotic agent over 6-8 weeks, with the goal of maintenance treatment with only one antipsychotic medication. Maintenance treatment with two antipsychotic medications (i.e., antipsychotic polypharmacy) is not advised due to a lack of evidence for efficacy as replicated in numerous studies, and evidence of significantly increased adverse effects.

In patients with neurodevelopmental disorders, slower antipsychotic taper (12-14 weeks) may be advised due to reported rebound symptomatology and agitation with more rapid taper (Baumeister, 1998; Kuijper, 2014).

Levels of Evidence for Efficacy in Child & Adolescent Psychopharmacology

This tool provides summary information for health care providers in determining levels of evidence for psychopharmacological treatment. Information summarized here is not reviewed at a level of detail to allow detailed inferences about specific medications within medication classes. For example, although there might be support for one medication within a class (e.g., SSRIs), there might be minimal or no support for others within that same class. For more specific information, please seek detailed reviews of specific medications and their use. FDA approved medications for a given indication are marked with an asterisk*

PROBLEM AREA	MEDICATION	SHORT-TERM EFFICACY	LONG-TERM EFFICACY
Anxiety Disorders	SSRIs	Α	В
	Benzodiazepines	С	С
OCD	SSRIs*	Α	С
ADHD	Stimulants*	Α	Α
	Atomoxetine* & TCAs	Α	В
	Central Adrenergic Agonists*	Α	С
Autism (for irritability and aggression)	Atypical antipsychotics *	А	В
Aggressive Conduct	Lithium	В	С
Problems with or without	Valproate	Α	С
ADHD	Carbamazepine	С	С
	Atypical antipsychotics	Α	В
Bipolar Disorder	Lithium*	Α	С
	Valproate	С	С
	Carbamazepine	С	С
	Atypicals*	Α	С
Depression	SSRIs*	Α	С
	TCAs	С	С
Treatment Resistant	Switching: SSRIs = Venlafaxine	В	С
MDD			
Schizophrenia	Antipsychotics*	Α	В
(psychotic disorders)			
Tourette's	Antipsychotics*	Α	С
	Central Adrenergic Agonists	В	С

A = Adequate data to inform prescribing practices. For efficacy and safety: $2 \ge$ randomized controlled trials (RCTs) in youth; long-term efficacy and safety are defined based on studies lasting 12 months or longer. Please note, for safety, "A" doesn't mean "safe", it merely indicates that the risks have been characterized in 2 or more carefully executed studies.

B = For short- and long-term efficacy and short-term safety: 1 RCT in youth or mixed results from \geq 2 RCTs. For long-term safety, only 1 careful prospective study lasting 12 months or more, or mixed results from \geq 2 longitudinal studies.

C = No controlled evidence or negative studies; case reports and FDA reports of adverse events only.

#=Safety category designations refer to whether sufficient data are available to determine the risks vs. benefits of treatment vis-à-vis the risks relatively common side effects. Very rare side effects cannot be anticipated and can sometimes be severe, so it cannot be assumed that the treatment benefits for a given child outweigh possible rare risks or side effects experienced by that child.

This table is provided for informational use, only by licensed health care providers, by The REACH Institute, www.TheReachInstitute.org. The table is not intended for use as a stand-alone guide but should only be used in conjunction with evidence-and consensus-based guidelines for specific disorders.

Adapted and used with permission from The Reach Institute Table last updated: December 20, 2018 -- Peter S. Jensen & M. Lynn Crismon

Glossary

Acronym/ Abbreviation	Definition
AACAP	American Academy of Child and Adolescent Psychiatry
ACEI	Ace inhibitor. Antihypertensive medication.
AIMS	Abnormal involuntary movement scale
ANC	Absolute neutrophil count
ARB	Angiotensin receptor blocker. Antihypertensive medication.
BID	Twice daily dosing (usually morning and evening, 10-12 hours apart)
ВМІ	Body mass index. A measure of body fat based upon height and weight
ВР	Blood pressure
BUN	Blood urea nitrogen
СВС	Complete blood count. Lab test used to monitor for abnormalities in blood cells, e.g., for anemia
CD	Controlled delivery
COX II inhibitors	Cyclooxygenase II inhibitor pain medication
Ср	Plasma concentration
CR	Controlled-release
СҮР	Cytochrome P450
EEG	Electroencephalogram
EIAED	Enzyme Inducing Anti-Epileptic Drugs (e.g. carbamazepine, phenobarbital, phenytoin, primidone)
EKG	Electrocardiogram
EPS	Extrapyramidal side effects. These are adverse effects upon movement, including stiffness, tremor, and severe muscle spasm
ER	Extended-release
FDA	U.S. Food and Drug Administration
GAD	Generalized anxiety disorder
HbA1c	Hemoglobin A1c is a laboratory measurement of the amount of glucose in the hemoglobin of the red blood cells. Provides a measure of average glucose over the previous 3 months
HR	Heart rate
IR	Immediate-release
Kg	Kilograms (1 kg is equivalent to 2.2 pounds)
LA	Long-acting Congruence
LFTs	Liver function tests
MAOI	Monoamine oxidase inhibitor
MDD	Major depressive disorder
MRI	Magnetic resonance imaging
Msec	Millisecond

Acronym/ Abbreviation	Definition
NRS	Neurological rating scale
NSAID	Non-steroidal anti-inflammatory drug
OCD	Obsessvie-compulsive disorder
ODT	Orally disintegrating tablet
PRN	As needed
Prolactin	A hormone produced by the pituitary gland
QD	Once daily dosing
Serum creatinine	A lab test used to calculate an estimate of kidney function
SL	Sublingual
SR	Sustained-release
SSRI	Selective serotonin reuptake inhibitor
TCA	Tricyclic antidepressant
TD	Transdermal
TFT	Thyroid function test
TID	Three times daily dosing (usually 6-8 hours apart)
UA	Urine analysis
XL	Extended-length
XR	Extended-release

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Members of the Workgroup

Chairs

 Nina Jo Muse, MD: Child Psychiatrist, Chief Medical Officer, State Hospital System, Texas Health and Human Services Commission, Austin, TX. M. Lynn Crismon, PharmD: Psychopharmacologist, Dean, James T. Doluisio Regents Chair & Behrens Centennial Professor, College of Pharmacy, Professor of Psychiatry, Dell Medical School, The University of Texas at Austin, Austin, TX.

Members

- Joseph Blader, PhD: Clinical Psychologist, Meadows Foundation & Semp Russ Professor of Child Psychiatry Research, Departments of Psychiatry and Pediatrics, The University of Texas Health Science Center at San Antonio, San Antonio, TX.
- Angela Hughes Campbell, PharmD: Psychopharmacologist, Adjunct Assistant Professor, College of Pharmacy, The University of Texas at Austin, Nacogdoches, TX.
- Caron E. Farrell, MD: Child Psychiatrist, Assistant Professor, Dell Medical School,
 The University of Texas at Austin, Austin, TX.
- Megan J. Gray, MD: Assistant Professor of Pediatrics, Dell Pediatric Research Center, The University of Texas at Austin, Austin, TX.
- Mark Janes, MD: Child Psychiatrist, Medical Director, Bluebonnet Trails Community Services, Round Rock, TX.
- Molly Lopez, PhD: Clinical Psychologist, Research Associate Professor, School of Social Work, The University of Texas at Austin, Austin, TX.
- Octavio N. Martinez, Jr., MD: Psychiatrist, Executive Director-Hogg Foundation for Mental Health, The University of Texas at Austin, Austin, TX.
- Sylvia Muzquiz-Drummond, MD: Child Psychiatrist, Medical Director MHMRA of Harris County, Houston, TX.
- Steven Pliszka, MD: Child Psychiatrist, Dielmann Distinguished Professor and Chair, Department of Psychiatry, The University of Texas Health Science Center, San Antonio, TX.
- Roberto Rodgriguez, MD: Pediatrician, Medical Director, Texas Department of Family and Protective Services, Austin, TX
- James A. Rogers, MD: Child Psychiatrist, Retired, Previous Medical Director, Texas Department of Family and Protective Services, Austin, TX.
- Rishi Shawhney, MD: Psychiatrist, Medical Director of Behavioral Health, Medical and Social Services Division, Texas Health and Human Services Commission, Austin, TX.

Committee Members Disclosures

Since January 1, 2013, the authors below disclose the following financial relationships:

- Dr. Blader has received funding as a consultant/researcher from Supernus Pharmaceuticals and research funding through his employer institution from Supernus.
- Dr. Crismon has nothing to declare.
- Dr. Lopez holds stock in Lilly, Merck, Proctor & Gamble, and Pfizer Pharmaceuticals.
- Dr. Pliszka has received funding as a consultant for Ironshore and Shire Pharmaceuticals. Through his employer institution he has served as an expert witness for Eli Lilly and Janssen Pharmaceuticals. He has received research grants through his employer institution from Ironshore, Purdue and Shire.
- The other members of the working group do not have any financial relationships to disclose.

Disclaimer

The authors of this document have worked to ensure that all information in the parameters is accurate at the time of publication and consistent with general psychiatric and medical standards and consistent with FDA labeling and information in the biomedical literature. However, as medical research and practice continue to advance, therapeutic standards may change, and the clinician is encouraged to keep up with the current literature in psychiatry and clinical psychopharmacology. In addition, not all potential adverse drug reactions or complications are listed in the tables, and the clinician should consult the official FDA labeling and other authoritative reference sources for complete information. These parameters are not a substitute for clinical judgment, and specific situations may require a specific therapeutic intervention not included in these parameters.

Acknowledgements

Laura Roccograndi (Pharm.D. Candidate, The University of Texas at Austin) assisted with the literature search and updating of the medication tables.

Brad Fitzwater, MD (Maternal & Child Health Medical Director, Texas Department of State Health Services) assisted with narrative regarding Medication Assisted Treatment.