Clinical Guidelines:

Prescribing and Monitoring of Antipsychotic Medications for Youth

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Community Behavioral Health
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1. INTRODUCTION

At the turn of the 21st century, the rate of antipsychotic medication prescribing increased nationally. Second-generation antipsychotics (SGAs) hold U.S. Food and Drug Administration (FDA)-approved indications for schizophrenia, bipolar disorder type 1, irritability associated with autistic disorder, and Tourette's disorder among specific pediatric age groups. Their use expands to off-label indications as well, such as adjunctive treatment in major depression. As rates of prescribing of SGAs increased, new evidence emerged suggesting safety and quality concerns in pediatric antipsychotic prescribing, including growing evidence of potential SGA-associated cardiometabolic side effects, limited discussions with families regarding risks and benefits of antipsychotic medications, and disproportionate prescribing patterns in specific vulnerable pediatric populations and geographic locations.[1]

To explore this national trend in the state of Pennsylvania, the Children's Hospital of Philadelphia (CHOP) Policy Lab conducted a study in 2015, *Antipsychotic Prescribing to Children in Pennsylvania.* Their study showed that children and adolescents (often referred to as "youth" in this document) enrolled in Medicaid have been disproportionately prescribed antipsychotics compared to children who are commercially insured. Additionally, approximately two-thirds (61%) of youth in child welfare custody who were prescribed antipsychotics did not have clinically indicated behavioral health diagnoses.[2]

In response to CHOP's findings, the Pennsylvania Department of Human Services (PA-DHS) and the Office of Medical Assistance Programs (OMAP) implemented the *Children's Electronic Antipsychotic Dashboard* to enhance the understanding and monitoring of psychotropic medication use within Pennsylvania's foster care population. These prescribing guidelines were developed in part to expand the state project by ensuring that all youth enrolled in Medicaid (not just those in foster care) who are receiving antipsychotic medications are being appropriately monitored and comprehensively treated.

To ensure CBH youth members receive the safest and highest quality psychiatric care available, the following prescribing guidelines have been developed. These guidelines are based on several nationally recognized prescribing guidelines and practice parameters. In particular, the American Academy of Child and Adolescent Psychiatry's *Practice Parameter on the Use of Atypical Antipsychotic Medications in Children and Adolescents* informs the following requirements.[3]

All CBH network providers who treat and care for youth (ages 0-17) are required to develop policies and procedures to ensure prescribing adheres to these guidelines.

2. REGARDING ASSESSMENT

A psychiatric evaluation providing a comprehensive overview of clinical formulation and subsequent treatment recommendations must be conducted prior to prescribing antipsychotics. This evaluation must clearly document

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[1] *Substance Abuse and Mental Health Services Administration:* ***Guidance on Strategies to Promote Best Practice in Antipsychotic Prescribing for Children and Adolescents****. HHS Publication No. PEP19- ANTIPSYCHOTIC-BP. Rockville, MD: Office of Chief Medical Officer. Substance Abuse and Mental Health Services Administration, 2019.*

[2] *Malone, M., MHS, Zlotnick, S., MSPH, MSW, Miller, D., JD, Kreider, A., Rubin, D., MD, MSCE, & Noonan, K., JD. (2015).* ***Psychotropic Medication Use by Pennsylvania Children in Foster Care and Enrolled in Medicaid****.*

[3] ***Practice parameter for the use of atypical antipsychotic medications in children and adolescents****.*

symptoms sufficient to support the documented diagnosis as well as the rationale for medical decision making, including prescribing. A plan to assess treatment response and adverse effects must also be documented.

Prior to prescribing antipsychotics, a psychiatric evaluation should be conducted, including a biopsychosocial assessment. The psychiatric evaluation should include a description of current behaviors and symptoms of concern, history of mental and physical health, family history, history of substance use (i.e. alcohol, stimulants, cannabis, benzodiazepines, and narcotics) as well as social history regarding context and functioning of the individual being assessed. All these components should be synthesized in a clinical formulation and treatment plan. This evaluation must clearly document symptoms sufficient to support the documented diagnosis as well as the rationale for proposed treatment plan, especially pharmacologic intervention. Finally, prior to treatment there should be documentation of a plan to assess treatment response (e.g., clinical scales specific to target symptoms) as well as adverse effects.

All youth who are treated with antipsychotic medications (including those whose medication is managed by a physician who is not a psychiatrist) should receive a minimum of one psychiatric evaluation annually. Additional evaluations may be indicated if the youth's psychosocial context changes significantly, symptoms remain the same or worsen despite treatment, or there is a need for increased monitoring of medication side effects, utilizing scales such as the Abnormal Involuntary Movement Scale (AIMS).

Core components of psychiatric evaluation[3]:

- **History of Present Illness**: Description of present problems and symptoms, including current interventions
- **Psychiatric history**: Information about prior conditions, admissions, and treatment, including response to treatment and side effects, if applicable
- **Medical history**: Information about health, illness, laboratory results (e.g., metabolic profile, lipid profile, diabetes screening, prolactin lab work), and treatment, including past and current medications
- **Family history**: Parent and family health and psychiatric histories, including suicide, psychiatric diagnoses, history of substance use disorders, and caregiver stability and ability to handle medical responsibilities
- **Developmental history**: Information about the child's development (e.g. in utero exposure, meeting of major milestones)
- **Education**: Information about school, performance (including grades repeated, suspensions or expulsions), screening for learning disabilities and individual education plan (IEPs)
- **Social history**: Information about current home, family relationships, social support, and stressors
- **Substance use history:** Information about current or past use of any substances and details related to use
- **Trauma history:** Information about physical, sexual, or emotional abuse
- **Mental Status Examination**: Observations and assessment of appearance, behavior, abnormal involuntary movements, mood, anxiety, psychotic symptoms, cognition, insight/judgment during interview with individual

The information synthesized in the evaluation should be obtained from a combination of these sources:

- Medical records

- Interview of the child or adolescent
- Interview of parents/guardians
- School staff, as deemed appropriate by provider

3. REGARDING FDA AND OFF-LABEL PRESCRIBING

When selecting any antipsychotic for use in a child or adolescent, a provider should follow the most current available evidence in scientific literature. The long-term simultaneous use of multiple antipsychotics has not been studied rigorously and generally should be avoided.

Antipsychotics are commonly prescribed off-label, meaning for an indication for which it does not have FDA approval, partly due to a lack of systematic study that determines efficacy or safety. Although use of antipsychotics off-label is not contraindicated, regular monitoring is critical to detect adverse effects, as well as to ensure that the medication is effective. Body weight, BMI, liver function tests, blood glucose, and lipid profiles should be obtained at baseline and monitored at regular intervals during treatment with an atypical antipsychotic. Certain atypical antipsychotics, such as clozapine, may require additional lab work to assess for safety and efficacy. Cardiovascular monitoring including EKG may also be indicated depending upon the patient's history and use of certain concomitant medications.

Antipsychotic medications are used widely for youth without FDA approved indications often to manage "off-label" aggressive or challenging behaviors.[1] Treatment may be "off-label" because of either the age of a child (e.g., 3-year-old child with severe autism) or the indication (e.g., treatment of aggression, mood instability, and irritability in an adolescent who is sub-threshold for a diagnosis of bipolar disorder). The limited safety and efficacy data to guide "off-label" treatment warrants careful consideration of the risk-to-benefit ratio of antipsychotic treatment prior to initiating medication and underscores the importance of informed consent from the patient's parents or guardians. Also, of note in managing safety, the dosing of antipsychotics should follow the "start low and go slow" approach with the goal of finding the lowest effective dose. If or when side effects do occur, a trial at a lower dose should be considered.

Atypical antipsychotics are not approved by the US Food and Drug Administration (FDA) for children younger than five years of age. The FDA approved indications for use of atypical antipsychotics in children include Schizophrenia, Bipolar I Disorder (manic/mixed episodes or adjunct therapy for depressive episodes), Tourette's Disorder, and Irritability related to Autistic Disorder.[4]

4. REGARDING DRUG SELECTION AND PRIOR AUTHORIZATION PROCESS

Antipsychotic medications are utilized for FDA-approved as well as off-label indications. To support the drug selection process, a detailed medication table is available in the **Appendix** with a comprehensive list of antipsychotic medications, along with dosing ranges and indicated ages for each medication.

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[4] *Center for Medicare and Medicaid Services Medicaid Integrity Group:* ***Atypical Antipsychotic Medications: Use in Pediatric Patients***.

An important element in the drug selection process is Prior Authorization (PA). PA is an administrative tool used by a health plan or prescription benefits management company that requires the prescribing clinician to receive approval prior to the medication being dispensed by a pharmacist.[1] Nationally, PA criteria are implemented to ensure appropriate utilization and minimize safety concerns for children who are prescribed antipsychotic medications. Pennsylvania has established a state-wide formulary[5] through its state-led Pharmacy and Therapeutics Committee for Medicaid Beneficiaries, which details prior authorization criteria for antipsychotic medications, as well as other medications.

The five scenarios outlined below will warrant submission of documentation to satisfy PA criteria[6] for antipsychotic medications in youths:

- A non-preferred antipsychotic. See the **Preferred Drug List (PDL)** for the list of preferred antipsychotics.
- An antipsychotic with a prescribed quantity that exceeds the quantity limit
- An antipsychotic when prescribed for a child under 18 years of age
- An atypical antipsychotic when there is a record of a recent paid claim for another atypical antipsychotic (therapeutic duplication)
- A typical antipsychotic when there is a record of a recent paid claim for another typical antipsychotic (therapeutic duplication)

5. REGARDING NON-PHARMACOLOGICAL BEHAVIORAL HEALTH TREATMENT

Psychotropic medication should be used as part of a multimodal treatment plan that also includes effective behavioral health therapy and other psychosocial interventions as determined by the psychiatrist and treatment team leader. Reference the **Monitoring** section for details regarding expectations for frequency of psychosocial treatment.

Disorders where psychotropic medications like antipsychotics are used can be broadly grouped in the following categories below. In addition, non-medication treatment modalities are provided, including information on local providers delivering these modalities in the Philadelphia region.[7]

5.1. For Children with Disorders in the Disruptive Behavior Disorder Spectrum

For children and youths with, or at high risk of developing, oppositional defiant disorder and conduct disorders, there are several interventions that could be attempted prior to or along with antipsychotic treatment. These behavioral treatments

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[5] *Office of Medical Assistance Programs;* ***Pennsylvania Medicaid Preferred Drug List****.*

[6] *Office of Medical Assistance Programs;* ***Pennsylvania Medicaid Prior Authorization Guidelines for Antipsychotic Medications****.*

[7] *Department of Behavioral Health and Intellectual disAbility Services.* ***Evidence-Based Practices in Philadelphia****.*

target child problems indirectly by reshaping parenting practices and disrupt negative coercive cycles by training parents to increase positive feedback for appropriate behaviors, to ignore disruptive behaviors and improve compliance.

5.1.1. Incredible Years

Incredible Years is a group of interlocking evidence-based programs which address the skills needed for caregivers, teachers, and children to increase the chances of academic success, strong interpersonal relationships, and healthy development in the child.

- **Additional Information about Incredible Years Treatment Modality with Case Examples**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver Incredible Years**

5.1.2. Parent–Child Interaction Therapy (PCIT)

PCIT is a treatment for young children and their caregivers that uses a coaching model to strengthen the parent-child relationship and build skills for behavior management.

- **Additional Information about PCIT Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver PCIT**

5.2. For Children with Disruptive Behaviors and Comorbid Trauma History

Treatments listed below can be considered to address trauma as well as ensure better affect regulation and management and skills building as well as specific therapies to address trauma.

5.2.1. Primary Child-Adult Relationship Enhancement (PriCARE)

PriCARE assists caregivers of children with disruptive behaviors or traumatic experiences in developing positive parenting skills and helps improve parent-child relationships.

- **Additional Information on PriCARE Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver PriCARE**

5.2.2. Child Parent Psychotherapy (CPP)

CPP helps caregivers of young children who have experienced trauma develop a strong, nurturing relationship with their child to restore the child's sense of safety and to support positive development.

- **Additional Information about CPP Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver CPP**

5.2.3. Child and Family Traumatic Stress Intervention (CFTSI)

CFTSI is a brief intervention for children who have experienced a potentially traumatic event. This intervention is aimed at preventing post-traumatic stress disorder symptoms by strengthening the family's ability to communicate and offer the child support.

- **Additional Information about CFTSI Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver CFTSI**

5.2.4. Trauma Focused Cognitive Behavioral Therapy (TF-CBT)

TF-CBT helps children and their caregivers overcome the impact of traumatic events through psychoeducation, creating a safe space to process the event, and developing new coping strategies.

- **Additional Information about TF-CBT Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver TF-CBT**

5.3. For Conduct Disorder in Youth

The focus of interventions for conduct disorder is at the family or systemic level. Some treatment modalities that are useful and available include:

5.3.1. Functional Family Therapy (FFT)

FFT is a family-based intervention aimed at changing the patterns of how families' members communicate, problem solve, and support one another.

- **Additional Information about FFT Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver FFT**

5.3.2. Multisystemic Therapy for Problem Sexual Behaviors (MST-PSB)

MST-PSB is a treatment for youth who have exhibited problematic sexual behavior. MST-PSB works with the whole family to address the behavior and develop skills and supports while keeping the youth in their community and maintaining the safety of others around them.

- **Additional Information about MST-PSB Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver MST-PSB**

Mood disorders are another class of disorders where antipsychotics are used as augmenting agents to reduce depression or for mood stabilization in bipolar disorders or personality disorders such as Borderline personality with significant mood instability. Psychosocial treatments that are helpful additional modalities complementing pharmacotherapy are:

5.3.3. Cognitive Behavior Therapy (CBT)

CBT is a solution-focused treatment that helps a person learn skills and solve problems by identifying unhelpful thinking patterns (cognitive distortions), changing inaccurate beliefs, engaging in new behaviors, and relating to others in more positive ways that support meeting their personal goals and recovery.

- **Additional Information about CBT Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver CBT**

5.3.4. Dialectical Behavior Therapy (DBT)

DBT helps individuals who have struggled with suicidal thoughts, self-harm, and emotion dysregulation to develop coping strategies and skills for committing to "a life worth living."

- **Additional Information about DBT Treatment Modality**
- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver DBT**

5.3.5. Applied Behavior Analysis (ABA)

ABA helps individuals with autism spectrum disorder (ASD) and learners with other special needs increase skills and behaviors that are not yet developed, decrease problematic behaviors that interfere with learning, and teach caregivers how to successfully manage challenging behaviors.

ABA and pharmacotherapy are used to treat aggression and self-injury associated with ASD. In many cases when there are clear antecedents to behaviors, ABA interventions, should be used to address them. When antecedents are unidentifiable, or behaviors are severe and challenging, concurrent pharmacotherapy may also be employed.

- **Contact Information of Providers in Philadelphia Area who are trained in and actively deliver ABA**

5.4. For Bipolar Disorder in Youth

5.4.1. Family-Focused Therapy

Family-focused therapy helps individuals who had an episode of mania or depression and were recently discharged from inpatient stay. Specifically, those transitioning to live with family or caregivers can benefit. The goal of family-focused therapy is to equip both the patient and caregiver(s) in navigating the patient's mental health condition.

- **Additional information on family-focused therapy**

6. REGARDING SHARED DECISION-MAKING TOOLS FOR YOUTH AND FAMILIES

When medication is being considered as part of a youth's treatment plan, it's imperative that the provider, the child, and their legal guardian come to a consensus about the treatment plan.

The Agency of Healthcare Research and Quality (AHRQ) recommends the SHARE Approach[8] to ensure that the health care provider, child, and child's legal guardian work together to make a health care decision that is best for the patient.

1. **Seek your Patient's Participation**

   Summarize the health and problem and let the child and their legal guardian know their options for their health issue. Ask for participation in making health care decisions and remind the child and legal guardian that their participation is important and necessary for optimal care.

2. **Help your Patient Explore and Compare Treatment Options**

   Discuss the benefits and risks of each treatment option. Assess what the child and their legal guardian know about their options and describe them in plain language. Offer evidence-based decision aid tools when possible and use visual aids (graphs, charts, pictographs) to help them understand your explanations. Summarize by listing the options and ask them to explain in their words what the options are.

3. **Assess your Patient's Values and Preferences**

   Encourage discussion about what is most important to the child and their family. Ask open-ended questions and listen to the child and their guardian. Agree on what is important and acknowledge the values and preferences that matter most to them, and factor what you learn into the medication selection process.

4. **Reach a Decision with your Patient**

   Guide the child and their legal guardian to express what matters most in deciding the best options. Ask if more supporting information is needed and check to see if more time is needed to consider their options.

5. **Evaluate your Patient's Decision**

   Monitor the extent to which the treatment decision is being implemented and assist with managing barriers to implementation. In follow-up appointments, revisit the decision with the child and their legal guardian and determine if other decisions need to be made.

Additionally, clinicians should understand the patient's and/or caregiver's cultural beliefs or stigma that may influence the youth's mental health treatment plan. The patient's care team should ensure that they are considering cultural factors when creating a treatment plan. Clinicians should ensure that the treatment option is not only presented in laymen language, but also in the language in which the child and caregiver are proficient.[9]

Providers should empower caregivers of youth to utilize CBH's infosheet, ***Antipsychotics Education for Parents and Caregivers***. This tool provides caregivers with background information and questions to ask when their youth is prescribed an antipsychotic medication. It encourages caregivers to ask questions to their youth's provider(s), outlines monitoring parameters, and lists tips to help their youth maintain adherence to medication.

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[8] ***The SHARE Approach: A Model for Shared Decisionmaking – Fact Sheet***. *Content last reviewed September 2020. Agency for Healthcare Research and Quality, Rockville, MD.*

[9] *Pumariega, A. J., Rothe, E., Mian, A., Carlisle, L., Toppelberg, C., Harris, T., Gogineni, R. R., Webb, S., & Smith, J. (2013).* ***Practice parameter for cultural competence in child and adolescent psychiatric practice***. *Journal of the American Academy of Child & Adolescent Psychiatry, 52(10), 1101–1115.*

7. REGARDING INTENSIVE CARE COORDINATION

Intensive care coordination across service systems is important for the optimization of treatment and overall well-being of youth with significant mental health and substance use conditions. Broadly, this refers to the establishment of an intensive family- and youth- driven care coordination system, which includes case management that is individualized and coordinated across youth serving entities relevant to a given individual. Care coordination interventions have been found to improve outcomes such as reduce concomitant antipsychotics prescribing and improve monitoring of metabolic side effects.

Different models of this type of service have been studied and expert consensus recommends the following guiding principles[1, 3]:

- Providing care coordination based on informed decisions of both the youth and caregivers
- Facilitate access to ancillary data about the patient's prior service utilization as able
- Assess fidelity to care coordination models and provide needed support and adjustments to that model to address challenges that may arise

Below are specific recommendations:

- Coordinate proactively between physical and mental health providers to holistically address complex needs of youth and families.
- Pay close attention to care gaps that often arise during times when youth are transitioning from higher levels of care (e.g., residential treatment) to community-based settings.
- Working closely with pharmacies to facilitate prior authorization processes that are often needed to access antipsychotic medications for youth. Medication selection should factor in the **Pennsylvania Medicaid Formulary**[5] to minimize barriers during transition of care. Case managers should ensure that prescribers are completing the necessary components of the prior authorization (e.g., lab work, physical, behavioral health evaluation) as necessary to prevent delays in medication treatment.
- Soliciting for support from Case Management early in the treatment process would allow for appropriate referrals to care as well as ancillary services (e.g., transportation, peer support groups) to ensure successful and sustainable linkages to recommended care.

8. REGARDING MONITORING OF TREATMENT

Psychotropic medication should not be used other than as part of a multimodal treatment plan that also includes effective behavioral health therapy and other psychosocial interventions as determined by the psychiatrist and treatment team leader.[3] The provider, in collaboration with caregivers, should develop clear target symptoms and goals. These should be the indices by which efficacy of treatment is determined.

Providers should adhere to the requirements of *CBH Bulletin 10-03: Use of Psychotropic Medications in Children and Adolescents (FDA-Approved and Off-Label)*.[10]

The lowest effective dose of antipsychotic medication should be used to minimize the risk of side effects while maintaining symptom control. If the medication is clinically effective, but mild to moderate side effects are present, slowly lowering the dose and examining the response is suggested. If the side effects are alleviated, gradually increasing the dose again can sometimes be considered. Monitoring should be intensified with initiation and upward dose titrations of antipsychotic medications.

8.1. Involuntary Movements

Some of the most concerning short and long-term side effects associated with these agents are movement disorders; thus, careful screening for their appearance is warranted. Providers must document the use (at baseline and every six months) of a standardized rating scale such as the Abnormal Involuntary Movement Scale (AIMS) or the Neurological Rating Scale (NRS). It is also prudent to provide psychoeducation on Extrapyramidal symptoms (EPS) and complications such as Neuroleptic Malignant Syndrome to individuals and families so that concerning developments can be addressed as early as possible.[3]

8.2. Metabolic Adverse Effects

Providers should adhere to the guidelines and monitoring discussed in *DBHIDS/CBH Bulletin 07-07: Screening for and Treatment of the Components of Metabolic Syndrome*.[11] Prior to initiation of treatment, clinicians should obtain personal and family history of diabetes, hyperlipidemia, seizures, and cardiac abnormalities. Based on these findings, metabolic side effect monitoring should be customized to the individual's risk profile recommends that clinicians obtain baseline measures of BMI, vital signs, blood glucose (preferably fasting) and monitor at regular intervals.

Additional measures of hemoglobin A1c and a lipid panel should be considered based on the individual risk of diabetes and hyperlipidemia. Regarding BMI specifically, this measure should be plotted on age specific diagrams [reference growth charts can be found on Center for Disease Prevention and Control's Growth Charts webpage.[12] If weight gain during treatment exceeds 90th percentile BMI for age or represents an increase of 5 BMI units, weight management interventions should be considered as well as an increased frequency of monitoring blood glucose and lipid levels. Long term use of antipsychotic medications may increase the risk of developing metabolic syndrome or related conditions.[13] Clinicians should monitor patients for components of metabolic syndrome routinely, as outlined in the bulletin linked above.

8.3. Cardiac Adverse Effects

Although limited data specifically addresses the cardiovascular impacts of atypical antipsychotic agents in children, the American Heart Association recommends that routine electrocardiograms (EKGs) may not be needed for all individuals;

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[10] ***CBH Bulletin 10-03: Use of Psychotropic Medications in Children and Adolescents (FDA-Approved and Off-Label)***.

[11] ***DBHIDS/CBH Bulletin 07-07: Screening for and Treatment of the Components of Metabolic Syndrome***.

[12] *Center for Disease Control and Prevention.* ***Growth Charts***.

[13] *Libowitz, M. R., & Nurmi, E. L. (2021).* ***The burden of antipsychotic-induced weight gain and metabolic syndrome in children***. *Frontiers in Psychiatry, 12.*

however, for those with a family history of cardiac abnormalities or sudden death, or a personal history of syncope, palpitations, or cardiovascular abnormalities, a baseline EKG and subsequent monitoring at a regular interval should be carefully considered.[14] Cardiac adverse effects may also develop after long-term use of antipsychotic medications, especially given the coexistence of metabolic and cardiac conditions.[13]

9. REGARDING CONSENT AND ASSENT

Informed consent is the legal process used to promote patient autonomy[15] and should include providing information to the legal guardian, the child/youth, engaging in an interactive discussion regarding the purpose, risks, benefits of medication (as well as specific points noted below) and the documentation of such discussion in the chart as well as a separate informed consent document signed by the appropriate parties.

A mechanism to obtain assent for psychotropic medication from minors must be established.[10] It is the responsibility of the prescribing psychiatrist to identify the parties who are legally empowered to consent for medication treatment of children and youth.

Careful attention must be paid to children and families with child welfare involvement and to custody arrangements that specify who the legal guardian is for medical care. When medication is being considered as part of the treatment plan, there should be an interactive, well-documented discussion with the patient (or the person authorized to make medical decisions on the patient's behalf) regarding:

1. The rationale for the benefits of an initial medication prescription, including the condition or targeted symptoms
2. The risks specifically associated with the proposed use, including adverse effects and a monitoring approach to ensure early intervention
3. If the selected medication is off-label, the nature of off-label use and the reasons for choosing a non–FDA-approved medication
4. If the medication also has a black box warning about its use, the clinician must discuss the nature of the black box warning as well as the regulatory requirements and monitoring schedules set forth by the FDA for these uses
5. Proposed strategy for tapering and or discontinuing the prescribed medication

Documentation of the discussion, informed consent document, along with any written materials provided to the patient, must be included in the child/adolescent's chart.[10]

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[14] Gutgesell H., Atkins D., Barst R., et al. (1999) AHA scientific statement: cardiovascular monitoring of children and adolescents receiving psychotropic drugs. Journal of the American Academy of Child and Adolescent Psychiatry. 38:1047-1050.

[15] Whitney SN, McGuire AL, McCullough LB. A typology of shared decision making, informed consent, and simple consent. Ann Intern Med. 2004 Jan 6;140(1):54-9. doi: 10.7326/0003-4819-140-1-200401060-00012. PMID: 14706973.

10. MONITORING

CBH encourages providers to maintain robust internal quality management programs to ensure treatment of CBH members adheres to these and other applicable guidelines. The goal of this CPG and all interventions developed as a result of it, is to promote safe and clinically optimal prescribing of antipsychotic medications to children and youths; and not to restrict or inhibit antipsychotic prescribing when appropriate and beneficial to a youth. In addition to as-needed reviews of records when quality issues arise, CBH will be tracking and sharing a standard National Committee for Quality Assurance (NCQA) HEDIS measure:

- APM (Metabolic Monitoring for Children and Adolescents on Antipsychotics)[16]: The percentage of children and adolescents (age 1-17) who had two or more antipsychotic prescriptions and had metabolic testing [blood glucose and lipid].

- Psychosocial Treatment for Children and Adolescents on Antipsychotics: The percentage of children and adolescents (age 1-17) with a new prescription for one or more antipsychotic medications who received at least 6 psychosocial treatments within 6 months of the prescription date.

In addition, providers must maintain documentation of all evaluations and interventions described in these guidelines, whether delivered by the provider or by an outside practitioner. CBH and the DBHIDS Network Improvement and Accountability Collaborative (NIAC) will continue to monitor treatment provided to ensure that care is consistent with the **DBHIDS Network Inclusion Criteria (NIC) Standards of Excellence**.

[16] *The National Committee for Quality Assurance (NCQA), Healthcare Effectiveness Data and Information Sets.* ***Metabolic Monitoring for Children and Adolescents on antipsychotics***.

11. APPENDIX: ANTIPSYCHOTICS MEDICATION TABLE[17,18]

Key things to know:

- If member has a history of hypersensitivity to any ingredients, it is a contraindication
- 1 kg = 2.2 lbs

Drug Name	***FDA Labeled Indication*** ** Off-Label Uses, Safe Dose Ranges* *** Contraindications/Unestablished Dosage*	***Age Criteria***	***Black Box Warnings*** *† Instructions*
Atypical Antipsychotics (Second Generation) *Common Side Effects: Weight Gain, Diabetes, Dyslipidemia, Hypotension, Sedation, Cardiac Effects, Hyperprolactinemia*			
Aripiprazole (Abilify®)	Schizophrenia 2-30 mg/day	13-17	Increased risk of suicidal thinking and behavior
	Bipolar I Disorder 2-30 mg/day	10+	
	Gilles de la Tourette's (orphan drug destination) IF <110 lbs/50 kg: 2-10 mg/day IF >110 lbs/50 kg: 2-20 mg/day	6-18	
	Autistic Disorder-Associated Irritability 2-15 mg/day	6-17	
Asenapine (Saphris®)	Bipolar I Disorder 2.5-10 mg/day	10-17	Increased risk of suicidal thinking and behavior Avoid eating or drinking 10 minutes after administration†
Clozapine (Clozaril®)	Safety and efficacy not established in children**	N/A	N/A
Iloperidone (Fanapt®)	Safety and efficacy not established in children**	N/A	N/A
Lurasidone (Latuda®)	Schizophrenia 40-80 mg/day	13-17	Increased risk of suicidal thoughts and behaviors

[17] ***UpToDate: Trusted, evidence-based solutions for modern healthcare***. *Wolters Kluwer*.

[18] ***UpToDate Lexidrug: Evidence-Based Drug Referential Content for Teams***. *Wolters Kluwer*.

Drug Name	*FDA Labeled Indication* ** Off-Label Uses, Safe Dose Ranges* *** Contraindications/Unestablished Dosage*	*Age Criteria*	*Black Box Warnings* *† Instructions*
	Bipolar I Disorder 20-80 mg/day	10-17	Take with food
Olanzapine (Zyprexa®)	Schizophrenia 2.5-20 mg/day	13-17	N/A
	Bipolar I disorder 2.5-20 mg/day	13-17	
	Depressed Bipolar I Disorder, in combination with Fluoxetine (Olanzapine/Fluoxetine) 2.5 mg/20 mg – 12 mg/50 mg per day	10-17	
	Chemotherapy-induced nausea and vomiting*		
Olanzapine/Fluoxetine (Symbyax®)	Depressed Bipolar I Disorder 3 mg/25 mg – 12 mg/50 mg per day	10-17	Increased risk of suicidal thoughts and behaviors Administer in the evening†
Paliperidone (Invega®)	Schizophrenia If <112.2 lbs/51 kg: 3-6 mg/day If >112.2 lbs/51 kg: 3-12 mg/day	12-17	N/A
Quetiapine (Seroquel®)	Manic Bipolar I Disorder Regular/IR: 25-600 mg/day ER: 50-600 mg/day	10-17	Increased risk of suicidal thoughts and behaviors
	Schizophrenia Regular/IR: 25-800 mg/day ER: 50-800 mg/day	13-17	
Risperidone (Risperdal®)	Autistic Disorder-Associated Irritability If 15-20 kg: 0.25-3 mg/day If >20 kg: 0.5-3 mg/day	5+	N/A
	Bipolar I Disorder 0.5-6 mg/day	10+	
	Schizophrenia 0.5-6 mg/day	13+	
	Autism Spectrum Disorder* Behavioral Syndrome-Mental Retardation* Gilles de la Tourette's Syndrome*	13+	

Drug Name	***FDA Labeled Indication*** ** Off-Label Uses, Safe Dose Ranges* *** Contraindications/Unestablished Dosage*	***Age Criteria***	***Black Box Warnings*** *† Instructions*
Ziprasidone (Geodon®)	Bipolar I Disorder If < 99 lbs/45 kg: 20-80 mg/day If > 99 lbs/45 kg: 20-160 mg/day	10-17	Take with food†
Typical Antipsychotics (First Generation) *Common Side Effects: Extrapyramidal Symptoms, Tardive Dyskinesia, Sedation, Prolactin Elevation*			
Chlorpromazine (Thorazine®)	Severe Problem Behavior Inpatient, Tablets: 50-200 mg/day Outpatient, Tablets: 0.56 mg/kg every 4-6 h Outpatient, Injection: 0.56 mg/kg every 6-8 h Inpatient, Injection: 50-200 mg/day	6 m-12 y	N/A
	Pre-Surgical Anxiety Tablets: 0.55 mg/kg, max dose 50 mg Injection: 0.55 mg/kg, max dose 25 mg	6 m-12 y	
	Nausea/Vomiting Tablet: 0.56 mg/kg Injection: 0.55 mg/kg/dose every 6-8 hours as needed MAX for 6 m-5 y: 40 mg/day MAX for 5 y-12 y: 75 mg/day	6 m-12 y	
Droperidol	Postoperative Nausea/Vomiting 0.01-0.05 mg/kg/day	2-12	Risk of QT prolongation and/or torsade de pointes
Fluphenazine (Prolixin®)	Contraindicated in pediatric patients under 12 years**	N/A	N/A
Haloperidol (Haldol®)	Behavior disorders, nonpsychotic (after failure of non-antipsychotic medication and psychotherapy) 3-12 y: 0.05-0.075 mg/kg/day in 2-3 divided doses >12 y: 0.5-6 mg/day in divided doses	3-12+	N/A
	Schizophrenia 3-12 y: 0.05-0.15 mg/kg/day in 2-3 divided doses >12 y: 0.5-15 mg/day in divided doses	3-12+	
	Severe Problematic Behavior (after failure of non-antipsychotic medication and psychotherapy) 3-12 y: 0.05-0.075 mg/kg/day >12 y: 0.5-5 mg	3-12+	
	Tourette Syndrome, tic disorder 0.05-0.075 mg/kg/day, max dose of 15 mg/day	3-12+	

Drug Name	***FDA Labeled Indication*** ** Off-Label Uses, Safe Dose Ranges* *** Contraindications/Unestablished Dosage*	***Age Criteria***	***Black Box Warnings*** *† Instructions*
Molindone (Moban®)	Schizophrenia 5-225 mg/day	12+	N/A
Perphenazine (Trilafon®)	Schizophrenia 8-64 mg/day in 2-4 divided doses	12+	N/A
Pimozide (Orap®)	Moderate to Severe Tourette Disorder 0.05-0.2 mg/kg/day (MAX: 10 mg/day)	12+	N/A
Prochlorperazine (Compro®)	Nausea/Vomiting 9-13.9 kg: 2.5-7.5 mg/day 14-18 kg: 2.5-10 mg/day 18.1-39 kg: 2.5-15 mg/day	12+	N/A
	Schizophrenia 2-5 y: 2.5-20 mg/day 6-12 y: 2.5-25 mg/day	2-12	
Thioridazine (Mellaril®)	Refractory Schizophrenia 0.5-3 mg/kg/day	6+	Prolong QTc interval
Thiothixine (Navane®)	Schizophrenia 6-60 mg/day in 2-3 divided doses	12+	N/A
Trifluoperazine (Stelazine®)	Schizophrenia Tablet: 1 mg-15 mg/day	6-12	N/A