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Oklahoma Clinical Care Guidelines
Atypical Antipsychotic Use for Members Under the Age of 5

INTRODUCTION

- ❑ **No atypical antipsychotic has FDA approval for use in children less than 5 years old, and only one antipsychotic has FDA approval for use in children less than 5 years old. There are no randomized controlled trials to demonstrate safety and efficacy in this population.**
- ❑ **In this age group, antipsychotics are typically prescribed for aggression and irritability associated with autism or disruptive behavior disorders as it is not recommended to diagnose a preschooler with bipolar disorder or schizophrenia.**
- ❑ **Appropriate non-pharmacological treatment should be tried before the use of antipsychotics is considered. Examples of therapies for disruptive behavior disorders include Parent Child Interaction Therapy (PCIT), Triple -P Positive Parenting Program, and Incredible Years. All therapies considered should be dyadic, including the child and the caregiver. Examples of therapies for children with autism spectrum disorders include those who have defiance, tantrums, and aggression includes PCIT. Applied Behavior Analysis can be used to identify the source of irritability or self-injurious behaviors. A complete workup is required for diagnosis and for an informed decision on appropriate treatment.**
- ❑ **Due to the sparsity of literature, these clinical guidelines provide guidance on reviewing stimulant prior authorizations for medical necessity for children under the age of 5.**

FDA APPROVED INDICATION

- ❑ **Aripiprazole**
  - Aripiprazole has many indications for adults and adolescents including treatment of psychotic disorders and bipolar disorders. Studies have indicated that this medication can also be helpful for irritability associated with autism spectrum disorders, and it is approved for ages 6 and up.
- ❑ **Risperidone**
  - Risperidone has many indications for adults and adolescents including treatment of psychotic disorders and bipolar disorders. Studies have indicated that this medication can also be helpful for irritability associated with autism spectrum disorders, and it is approved for ages 5 and up.

GENERAL APPROVAL CRITERIA

Atypical Antipsychotic medications for children under 5 years of age are medically necessary when the following criteria are met:

- ❑ **Child diagnosed, per current DSM criteria, with one of the following disorders:**
  - Autism Spectrum Disorder with documented irritability and/or aggression

- Disruptive Behavior Disorders

- ❑ **Documentation of the following monitoring parameters set by the American Diabetes Association to ensure patient safety from known adverse effects:**
  - Weight (BMI): baseline, four weeks, eight weeks, 12 weeks, then quarterly
  - Waist circumference: baseline, then annually
  - Blood pressure: baseline, 12 weeks, then annually
  - Fasting plasma glucose or A1c: baseline, 12 weeks, then annually
  - Fasting lipid profile: baseline, 12 weeks, and then every five years
  - Prolactin level should be assessed if symptomatic.
  - AIMS (Abnormal Involuntary Movement Scale): every six to 12 months.
- ❑ **A trial of aripiprazole or risperidone prior to other agents being approved.**
- ❑ **The requested dose does NOT exceed the dosing guidelines below.**
  - Dosing
    - Risperidone: Starting dose is 0.125mg. Maximum dose is 1.5 mg/day. Dosing range for risperidone is not established for children under six.
    - Aripiprazole: Starting dose is 1mg/day. Maximum dose is 7.5mg/day. Dosing range for aripiprazole is not established for children under six.

Additional Criteria for Initial Prescription Approval

Atypical Antipsychotic medications for children under 5 years of age are medically necessary for an initial prescription of an antipsychotic when the following criteria are met:

- ❑ **Provider must submit documentation (including office chart notes and lab results) of the below items:**
  - A child psychiatry evaluation by a child psychiatrist OR consultation with a child psychiatrist with a recommendation of an atypical antipsychotic trial.
  - Psychosocial issues and non-medical interventions are being addressed by the clinical team.
  - Documentation of comprehensive assessment occurring before request for atypical antipsychotic medications including:
    - An assessment of the full range of psychiatric symptoms and disorders, as well as impairment from these symptoms and disorders.
    - A full developmental assessment.
    - A full medical history, including a sleep history.
    - A relevant medical work-up, physical examination and nutritional status evaluation.
    - If relevant, an assessment of school functioning including academic, behavioral, and social aspects.
    - An assessment of family psychiatric history, which includes past and current history of parental psychiatric illnesses, substance abuse and treatment history of parents, caregivers, siblings, and other relatives.
    - An assessment of family structure and functioning, parent-child relationship, and interaction.
    - An assessment of environmental risk factors and stressors including any history of abuse (physical, sexual) or neglect, traumatic life events, domestic violence, economic instability, etc.
  - Documentation of non-medication alternatives, evidence based psychotherapeutic interventions that have been attempted to address symptoms for 3-6 months before request for antipsychotic medications.
  - Documentation must include information on the expected outcomes and an evaluation of potential adverse events.

Additional Criteria for Reauthorization, Dose Changes and Formulation Changes

Atypical Antipsychotic medications for children under 5 years of age are medically necessary for a reauthorization, dose change, or formulation change when the following criteria are met:

- ❑ **Provider must submit documentation (including office chart notes and lab results) of the below items:**
  - Member has previously met initial approval criteria.
  - Psychosocial issues and non-medical interventions are being addressed by the clinical team.
  - ADA monitoring parameters are being followed. (See General Approval Criteria above)
  - Comprehensive follow up visits including:
    - Assessment of symptoms with side effects noted.
    - Positive response to therapy [labs, sign/symptom reduction, etc.]
  - If documentation shows that the member has been stable on the medication for a year or more, a discontinuation has been considered and if clinically indicated, attempted.
- ❑ **If the request is a dose increase, the new dose does not exceed FDA approved maximum daily dose.**
- ❑ **If the request is a change to an alternative atypical antipsychotic:**
  - A trial of low dose aripiprazole and low dose risperidone are tried prior to other agents being approved.
  - A cross taper plan has been documented.

Length of Approval

6 months

References

1. Florida Medicaid Drug Therapy Management Program for Behavioral Health. Principles of Practice Regarding the Use of Psychotherapeutic Medication in children Under 6. http://www.medicaidmentalhealth.org/; http://www.medicaidmentalhealth.org/assets/file/Guidelines/POP_ASD&ID_Under%206.pdf
2. Arizona Health Complete Health Clinical Policy: Antipsychotic Medications in Children Under 6 years Old. Last review date 07/01/2019. Accessed 4/24. https://www.azahcccs.gov/PlansProviders/Downloads/GM/ClinicalGuidanceTools/PsychiatricandPsychotherapeuticBestPracticesforChildrenBirthThroughFiveYearsofAge.pdf
3. Gleason, M. Egger, H., Emslie, G., Greenhill, L., et al. (2007) Psychopharmacological treatment for very young children: Contexts and guidelines. Journal of the American Academy of Child & Adolescent Psychiatry, 46:1532–1572.

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