

**DUR
PROJECT****May 2012****Affected Programs:** BadgerCare Plus, Medicaid**To:** Advance Practice Nurse Prescribers with Psychiatric Specialty, Nurse Practitioners, Pharmacies, Physician Assistants, Physicians

Antipsychotic Drug Use in Children and Adolescents — Wisconsin Medicaid and BadgerCare Plus Population

In the past decade there has been a remarkable increase in the prescribing of antipsychotic medications to children and adolescents in the United States. An epidemiological study by the Food and Drug Administration (FDA), published in December 2009, revealed a 65 percent increase in the prescribing of antipsychotic medications to children 17 years of age and younger during the seven year period of 2002-2009.¹ Wisconsin has seen an increase of about 50 percent in the use of antipsychotic medications in children 17 years of age and younger during the period of 2002-2006. Due to growing concerns surrounding the use of antipsychotic medications in children and adolescents, the Wisconsin Drug Utilization Review (DUR) Program has prepared this publication as a clinical resource for prescribing.

In 2007, a study conducted by Rutgers Center for Education and Research on Mental Health Therapeutics provided an analysis of antipsychotic medication use among 12 million children and adolescents and concluded the following²:

- Many children receive mental health care that is largely limited to medications without adequate evaluations and other therapy services.
- The signs, symptoms, and diagnostic criteria for bipolar disorder in children are highly controversial and often lead to antipsychotic use in children and adolescents.
- There are many concerns about the use of multiple psychoactive medications simultaneously (polypharmacy) within and between drug classes.
- Off-label prescribing of antipsychotic medications in children occurs and some children are prescribed doses that may exceed maximum limits.
- Antipsychotic prescribing occurs in young children with questionable diagnoses and without child psychiatric consultation.
- There is limited knowledge about the long-term effects of antipsychotic medications.
- Children in foster care appear to have significantly higher rates of antipsychotic medication use.
- There are significant metabolic risks including weight gain and diabetes associated with the use of second generation antipsychotic medications.

Wisconsin is among many states who are adopting different approaches singularly or in combinations to better manage this medication use. These approaches include prior authorizations (PAs), preferred drug lists, restrictions by provider types, step therapy protocols, guidelines, limited refills, second opinions, age restrictions, dose restrictions, polypharmacy restrictions, cost restrictions, and generic preferences. There is growing concern particularly regarding the use of antipsychotic medications in children placed in foster care^{3,4} and in very young (6 years of age and under) preschool-age children.^{5,6}

Clinical Considerations

Clinical Management and Monitoring

Critical to the use of antipsychotics in children and adolescents is a clear knowledge of the risks, potential side effects, and standards of care for monitoring the use of these medications.^{7,8} In particular, routine use of Body Mass Index (BMI) is critical for monitoring weight gain, which may be associated with elevated glucose and lipids.⁹ Potential side effects including elevated prolactin levels and movement disorders should also be monitored. A helpful resource summarizing the drug monitoring concerns is available from the Texas Department of Family and Protective Services.¹⁰

Disorders for Potential Antipsychotic Use

The increase in the use of atypical antipsychotics, also known as second generation antipsychotics, is most likely due to targeting aggressive or impulsive behaviors in children. Children with one or more of the following disorders might receive treatment with atypical antipsychotics:

- Autistic Spectrum Disorders.
- Bipolar Spectrum Disorders.
- Developmental Disorders.
- Attention Deficit Hyperactivity Disorder (ADHD) and Disruptive Behavior Disorders such as Oppositional Defiant Disorder and Conduct Disorder.
- Psychotic Disorders.
- Tourette's or other Tic Disorders.

Autistic Spectrum Disorders

The use of antipsychotic medications for irritability, explosive behaviors, repetitive behaviors (stereotypies), and hyperactivity/noncompliance in some children and adolescents with autism spectrum disorders has support through clinical research, although more evidence-based practice guidelines are needed.^{11, 12, 13}

Bipolar Spectrum Disorders

Antipsychotic medications are increasingly prescribed alone or in concert with other psychoactive medications for bipolar spectrum disorders. This remains a very controversial area of child psychiatry as researchers continue to try to differentiate disorders of mood dysregulation from disorders that evolve into bipolar disorders as recognized in adult populations.^{14, 15, 16, 17} This state is captured succinctly by Dr. Robert Althoff in his editorial in the Journal of the American Academy of Child and Adolescent Psychiatry titled "Dysregulated Children Reconsidered" stating:

What child and adolescent psychiatrist has not had the case of a child who is profoundly dysregulated in multiple domains but does not meet the DSM-IV criteria for bipolar disorder? Until we study these children carefully ... we will continue shooting in the dark with our treatments. We owe more to these profoundly affected children.¹⁸

Developmental Disorders

Another group of profoundly affected children are those with severe developmental delays who are sometimes treated for aggressive or self-injurious behaviors with antipsychotic medications. The state of Florida has published guidelines for treating this population.¹⁵

ADHD and Disruptive Behavior Disorders

There are clinical situations where it may be appropriate to add an antipsychotic medication for a child with ADHD and a comorbid condition presenting with aggressive behaviors.¹⁹ Several state Medicaid programs have addressed the use of antipsychotic medications for aggressive behaviors in youth and published guidelines for treatment of this clinically heterogeneous population.^{15, 20, 21, 22}

Psychotic Disorders

There is a clinically sound role for antipsychotic medications for schizophrenia presenting in children and adolescents.²³

Tourette's or Other Tic Disorders

Antipsychotic medications are also indicated for the treatment of Tourette's or tic disorders.²⁴

Wisconsin's DUR Response

To address the use of antipsychotic drugs in children, Wisconsin has undertaken a multi-phased approach. The most recent phase involved the implementation of PA policy for children 6 years of age and younger who are prescribed an antipsychotic drug.

Providers may refer to the January 2012 *ForwardHealth Update* (2012-01), titled "New Prior Authorization Policy for Antipsychotic Drugs for Children 6 Years of Age and Younger," and the ForwardHealth Online Handbook on the ForwardHealth Portal at www.forwardhealth.wi.gov/ for more information about drug coverage policy and procedures.

An electronic copy of this DUR Newsletter can be found on Wisconsin Drug Utilization Drug Board page on the ForwardHealth Portal at www.forwardhealth.wi.gov/WIPortal/content/Provider/medicaid/pharmacy/dur/meetings.htm.spage.

Wisconsin's DUR Program has organized an extensive list of clinical information and reference materials for providers involved in the behavioral health care of children and adolescents. Annotations have been included to help guide the reader.

Additional Resources

Evidence-Based Treatments

2003 Review of the State of Evidence-Based Treatments in Child Psychiatry. McClellan, J. and Werry, J. "Evidence-Based Treatments in Child and Adolescent Psychiatry: An Inventory." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 42(12). Dec. 2003. pp. 1388-1400.

A review of evidence-based therapies in child psychiatry and the challenges and barriers to developing evidence-based therapies in the developing field of Child and Adolescent Psychiatry.

General Use of Psychotropic Medications in Children

"Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 48(9). Sept. 2009. pp. 961-973.

General parameters on use of psychotropic medications in children — choice of medications; duration of therapy; monitoring of side effects; identifying target symptoms; polypharmacy; etc.

Guidelines for Management of Medications — Children and Adolescents

Guidelines for Children — USF Medicaid Drug Therapy Management Program for Behavioral Health.

(http://flmedicaidbh.fmhi.usf.edu/recommended_child_guidelines.htm)

A good site to review approaches to several psychiatric disorders by a Medicaid program (referenced below #s 12, 18, 22).

Parent Training Program for Managing Children with Autism

Johnson, CR, et.al. "Development of a Parent Training Program for Children with PDD." Behavioral Interventions. Vol. 22. 2007. pp. 201-221.

Treating Pediatric Insomnia

Owens, J. "Pharmacotherapy of Pediatric Insomnia." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 48(2). Feb. 2009. pp. 99-107.

References

1) An FDA Report on Atypical Antipsychotic Drug Use in the U.S. Outpatient Pediatric Population (2002-2009).

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM272641.pdf>

An FDA study based on retail pharmacy databases noted increase in prescriptions of antipsychotic medications from 2.9 million to 4.8 million prescriptions. Especially notable is the off-label use for children with diagnoses of ADHD, which represented 12 percent of antipsychotic prescriptions written in 2009.

2) Antipsychotic Medication Use in Medicaid Children and Adolescents: Report and Resource Guide from a 16-State Study

http://rci.rutgers.edu/~cseap/MMDLNAPKIDS/Antipsychotic_Use_in_Medicaid_Children_Report_and_Resource_Guide_Final.pdf

Thorough study of antipsychotic use in Medicaid populations in 16 states from 2004 through 2007 with identification of major concerns and a survey of efforts in 36 states to improve safety and quality regarding the use of antipsychotics in children.

3) http://www.dfps.state.tx.us/Child_Protection/medical/default.asp#psychotropic/

From the Texas State Department of Family and Protective Services, a 2010 publication noting the particular concerns facing the mental health care of children in foster care. Publication reviews indications and monitoring of most psychoactive medications prescribed for children and notes criteria for the closer review of particular prescribing practices.

4) Multi-State Study on Psychotropic Medication Oversight in Foster Care

<http://tuftsetsi.org/~media/Files/CTSI/Library%20Files/Psychotropic%20Medications%20Study%20Report.ashx>

A study (September 2010) by the Tufts Clinical and Translational Science Institute that noted concerns about the use of psychoactive medications in children in foster care in 47 states. The study reviews policies and guidelines in use in 47 states regarding the monitoring and prescribing of medications as well as challenges of providing mental health services to children in foster care and child welfare systems.

- 5) Gleason, Mary, et.al. "Psychopharmacological Treatment for Very Young Children: Contexts and Guidelines." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 46(12) December 2007. pp. 1532-1572.

A very thorough review of evidence-based studies of psychoactive medication use for various disorders of children under 7 that includes suggested algorithms for the approach to ADHD, Disruptive Behavior disorders, Depression, Bipolar disorder, Anxiety disorder, Post-traumatic Stress Disorder, Obsessive-compulsive disorder, Pervasive Developmental disorder, and Sleep disorders.

- 6) Egger, Helen. "Perilous Disconnect: Antipsychotic Drug Use in Very Young Children." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol.49(1). Jan.2010. pp. 3-6.

An editorial describing the need for best practice guidelines for the use of psychoactive medications in children under 6 years.

- 7) Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents available at www.aacap.org/

The American Academy of Child and Adolescent Psychiatry posts several practice parameters addressing many different clinical issues on this Web site. Helpful "Facts for Families" series of educational fact sheets for public use is available on this site as well.

- 8) Correll, C. "Antipsychotic Use in Children and Adolescents: Minimizing Adverse Effects to Maximize Outcomes." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 47(1). Jan. 2008. pp. 9-20.

An excellent review of potential antipsychotic medication side effects and suggested guidelines for monitoring these medications in children.

- 9) <http://apps.nccd.cdc.gov/dnpabmi/>

A link for the easy calculation of BMI.

- 10) <http://www.dfps.state.tx.us/documents/about/pdf/TxFosterCareParameters-December2010.pdf>

From the Texas State Department of Family and Protective Services, a 2010 publication noting the particular concerns facing the mental health care of children in foster care. Publication reviews indications and monitoring of most psychoactive medications prescribed for children and notes criteria for the closer review of particular prescribing practices.

- 11) Aman, Michael, et.al. "Medications and Parent Training in Children with Pervasive Developmental Disorders and Serious Behavior Problems." Journal of the Am. Acad. Of Child and Adolescent Psychiatry. Vol. 48(12), Dec. 2009. pp. 1143-54.

Paper on integrating psychosocial interventions and medications for Pervasive Developmental disorder spectrum symptoms.

- 12) Kratochvil, C., et.al. "Pharmacological Management of Agitation and Aggression in an Adolescent with Autism." Journal of the Am. Acad. Of Child and Adolescent Psychiatry. Vol.44(8). Aug. 2005. pp. 829-32.

A case study with several different child psychiatrists sharing their approach to the use of medications to target agitation and aggression for a 13 year old with Pervasive Developmental disorder.

- 13) McDougle, Christopher; Posey, David. "Genetics of Childhood Disorders: XLIV. Autism, Part 3: Psychopharmacology of Autism." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol.41(11). Nov. 2002. pp. 1380-83.

Survey of various psychoactive medications targeting symptoms and behaviors in individuals with Pervasive Developmental disorder.

- 14) "Practice Parameter for the Assessment and Treatment of Children and Adolescents with Bipolar Disorder." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol.46(1). January 2007. pp. 107-125.

A review of assessment and treatment of pediatric bipolar disorder including a discussion of the controversy of whether juvenile mania is the same illness as adult bipolar disorder and what are the differences between anger/ aggressive symptoms and mania in children.

- 15) Guidelines for Children — USF Medicaid Drug Therapy Management Program for Behavioral Health.
(http://fmedicaidbh.fmhi.usf.edu/recommended_child_guidelines.htm)

A well-documented source of guidelines for evaluation and treatment of various mental disorders in children and adolescents.

- 16) Stringaris, A., et.al. "Pediatric Bipolar Disorder Versus Severe Mood Dysregulation: Risk for Manic Episodes on Follow-Up." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol.49(4). April 2010. pp. 397-405.

A recent discussion of the attempt to clarify some of the diagnostic challenges and inconsistencies in the concept of pediatric bipolar disorder.

- 17) Liu, H., et.al. "Pharmacologic Treatments for Pediatric Bipolar Disorder: A Review and Meta-Analysis." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 50(8). Aug. 2011. pp. 749-762.

Extensive review of medications for pediatric Bipolar disorder.

- 18) Althoff, Robert. "Dysregulated Children Reconsidered." Journal of the Am. Acad. Child and Adolescent Psychiatry. Vol. 49(4). April 2010. pp. 302-305.

An editorial on the differences between the concept of severe mood dysregulation versus pediatric bipolar disorder.

- 19) Pliszka, S., et.al. "The Texas Children's Medication Algorithm Project: Revision of the Algorithm for Pharmacotherapy of Attention-Deficit/Hyperactivity Disorder." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 45(6). June 2006. pp. 642-657.

A thorough presentation of algorithms developed by the Texas Department State Health Services for the treatment of ADHD and various comorbid conditions that addresses the role of antipsychotic medications when treating children who are aggressive and have ADHD.

- 20) The Treatment of Maladaptive Aggression in Youth (T-May) available at https://www.documentforsafety.org/kids/pub/forms/T-MAY_20110201.pdf

Guidelines for the treatment of aggression in youth that addresses target symptoms across many diagnostic categories. A resource developed in part by the North Carolina Division for Medical Assistance.

- 21) Schur, S., et.al. "Treatment Recommendations for the Use of Antipsychotics for Aggressive Youth, Part 1." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 42(2). Feb. 2003. pp. 132-144.

Review and guidelines for the evaluation and treatment of aggression in youth.

- 22) Pappadopulus, E., et.al. "Treatment Recommendations for the Use of Antipsychotics for Aggressive Youth, Part 2." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 42(2). Feb. 2003. pp. 145-161.

Review and guidelines for the evaluation and treatment of aggression in youth.

- 23) "Practice Parameter for the Assessment and Treatment of Children and Adolescents with Schizophrenia." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 40(7). Supplement, July 2001.

A thorough review of the assessment and treatment of schizophrenia in children and adolescents including differential diagnostic issues, target symptoms, treatment approaches, and medication monitoring.

- 24) Swain, James, et.al. "Tourette Syndrome and Tic Disorders: A Decade of Progress." Journal of the Am. Acad. of Child and Adolescent Psychiatry. Vol. 46(8). Aug. 2007. pp. 947-968.

A review of the assessment and treatment of tic disorders and comorbid conditions that discusses the role of various medications including antipsychotics.