Antipsychotic Peer Review Project

Background

The use of antipsychotic agents has increased substantially over the past decade particularly in children and adolescents.[1] In the United States, from 1993 to 2002, outpatient antipsychotic medication prescriptions for patients age 20 years and younger increased approximately 6-fold.[2] This increase was largely attributable to the atypical antipsychotics, which were prescribed for a variety of indications, including mood disorders, disruptive behavior disorders, developmental disorders, and psychosis. Approximately 1% of outpatient pediatric visits in 2003-2004 resulted in a prescription of an antipsychotic agent, primarily atypical antipsychotics.[3] Overall, the use of antipsychotic agents in pediatric populations is much higher in the United States than anywhere else in the world.

There is increased public scrutiny, controversy, and debate regarding the increasing use of the antipsychotic agents in children and the lack of data on long-term effects.[4] The majority of outpatient pediatric prescriptions, including psychotropic, are "off label."[5] The increased use of antipsychotic agents coincides with a marked increase in the diagnosis of bipolar disorder in youth,[6] which is also controversial.[7] Although there are a number of studies examining the use of antipsychotic medications in youth, most of the data result from short-term analysis or are derived from studies that have significant methodological limitations. The long-term efficacy and safety of these agents in the pediatric population has not been well established for any given clinical indication. Moreover, a number of investigations by the Senate Finance Committee and other sources have raised questions about the pharmaceutical industry and potential conflicts of interest by academic investigators whose work has promoted the use of these medication treatments in children and adolescents.

For the individual practitioner, the most pressing clinical issue is not whether antipsychotic medications are prescribed too often or too little, but rather what specific treatment is needed for a given child. Clinicians need to be familiar with the strengths and limitations of the empirical evidence supporting the use of different agents for different indications, as well as their adverse event profile and monitoring requirements.

Antipsychotics in Maryland

The table below reflects the number of prescriptions and unique Maryland Medicaid recipients by age group that had a claim prescribed off-label, based on the FDA age-approved indication between January 1, 2010 and December 31, 2010.

Age	# of Rxs	# of Children
0 - 4	705	178
5 - 9	12,992	2,065
10 - 12	11,699	1,824
13 - 17	19,349	2,875

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Medicaid Antipsychotic Peer Review Project

For the all the reasons mentioned above, effective October 1, 2011, the Maryland Medicaid Pharmacy Program (MMPP) is implementing a peer-review authorization process to ensure the safe and effective use of antipsychotics in children. The peer review will inform clinicians of relevant clinical information for decision-making and ensure the appropriate use while limiting adverse sequelae in Medicaid's vulnerable pediatric patients. Claims for antipsychotic medications that are for children younger than the FDA approved age, will require a Prior Authorization (PA) based on the peer-review assessment.

The MMPP's Board-Certified child psychiatrist will oversee the peer-review project. Furthermore, MMPP has contracted with the University of Maryland (UMD) Division of Child and Adolescent Psychiatry and School of Pharmacy to provide call center services. The UMD will utilize appropriate personnel (psychiatrists and pharmacists) to answer calls from Medicaid prescribers who prescribe antipsychotic medications off-label to children and provide timely clinical reviews of patient profiles to determine if the Program will approve or deny the claim.

If there is a denial of the PA by the Clinical Pharmacist then the reconsideration process is handled by the UMD's Child and Adolescent Psychiatrist.

If there is a denial of the PA by the UMD's Clinical Psychiatrist then the reconsideration process is handled by the State's Clinical Psychiatrist.

The MMPP will implement a "hard" edit which will prevent a claim for an antipsychotic drug from processing, when is determined that it does not meet the FDA approved age. This edit will occur at the Point of Service. The pharmacy provider will then have to contact the prescriber to inform them that the Program does require a peer review and consultation and therefore, they will need to call the peer-review call center and provide them with the telephone number to call. The prescriber will in turn contact the call center and upon completing the PA form, will receive consultation from the call center, and ultimately a decision related to the PA (approve/deny). The project will be implemented in three phases:

- Phase I – Apply off-label use edit for children ages 0 – 4
- Phase II – Apply off-label use edit for children ages 5 – 9
- Phase III – Apply off-label use edit for children ages > 10

Before MMPP turns on the edit in the claims processing system the Program will work with the Mental Hygiene Administration on outreach activities to prescribers, as well as families whose children are currently taking off-label antipsychotics. MMPP believes that with broad provider outreach and education prior to the implementation of the PA process, prescribers will request a PA before sending a family to the pharmacy with a prescription.

Goals and Objectives

Some of the major clinical goals and objectives of the Antipsychotic Peer Review Project are:

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1. Change prescribing patterns (age, drug class, and shift in medication utilization) without compromising children's access to mental health care;

2. Educate the provider community about pharmacologic and non-pharmacological resources for the treatment and management of children and adolescents served in the Maryland Medicaid program;

3. Enhance the use of evidence-based practices (including monitoring) in the treatment and management of children and adolescents served in the Maryland Medicaid program.

References

1. Vitiello B, Correll C, van Zwieten-Boot B, Zuddas A, Parellada M, Arango C. Antipsychotics in children and adolescents: Increasing use, evidence for efficacy and safety concerns. Eur Neuropsychopharmacol. 2009 May 23, Epub.
2. Olfson M, Blanco C, Liu L, Moreno C, Laje G. National trends in the outpatient treatment of children and adolescents with antipsychotic drugs. Arch Gen Psychiatry. 2006;63:679-685. Abstract
3. Aparasu RR, Bhatara V. Patterns and determinants of antipsychotic prescribing in children and adolescents, 2003-2004. Curr Med Res Opin. 2007;23:49-56. Abstract
4. Parens E, Johnston J. Understanding the agreements and controversies surrounding childhood psychopharmacology. Child Adolesc Psychiatry Ment Health. 2008;2:5.
5. Bazzano AT, Mangione-Smith R, Schonlau M, Suttorp MJ, Brook RH. Off-label prescribing to children in the United States outpatient setting. Acad Pediatr. 2009;9:81-88. Abstract
6. Moreno C, Laje G, Blanco C, Jiang H, Schmidt AB, Olfson M. National trends in the outpatient diagnosis and treatment of bipolar disorder in youth. Arch Gen Psychiatry. 2007;64:1032-1039. Abstract
7. McClellan J. Commentary: treatment guidelines for child and adolescent bipolar disorder. J Am Acad Child Adolesc Psychiatry. 2005;44:236-239. Abstract